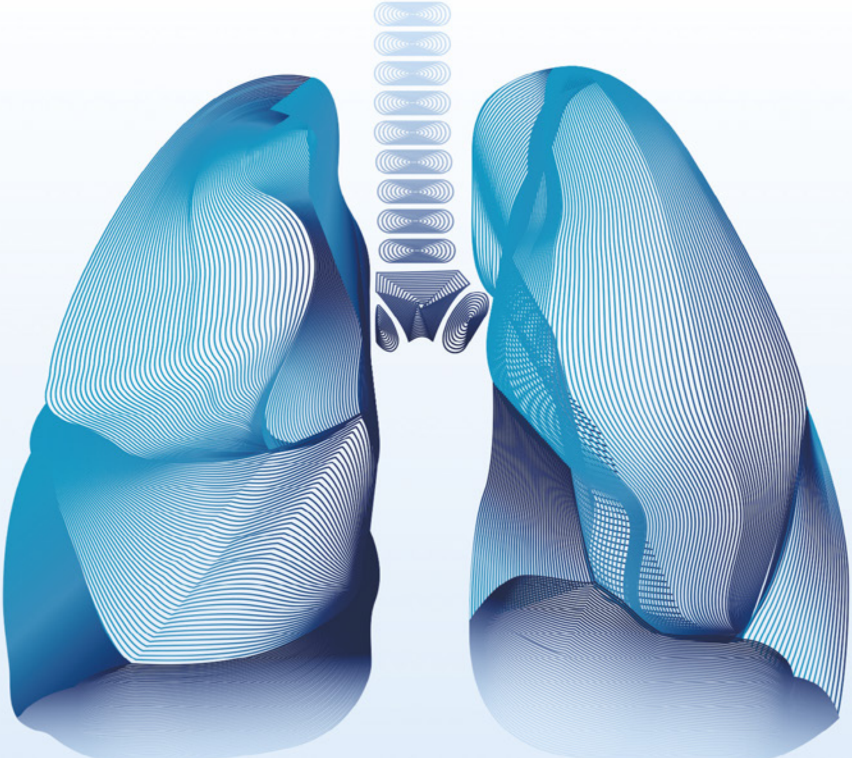
Environmental and Occupational Health Series

Handbook of Respiratory Protection

Safeguarding Against Current and Emerging Hazards



Edited by LeeAnn Racz
Dirk P. Yamamoto · Robert M. Eninger

CRC Press
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Handbook of Respiratory Protection

Safeguarding against Current and Emerging Hazards

ENVIRONMENTAL AND OCCUPATIONAL HEALTH SERIES

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Handbook of Respiratory Protection: Safeguarding Against Current and Emerging Hazards
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Perfluoroalkyl Substances in the Environment: Theory, Practice, and Innovation
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CRC Press
Taylor & Francis Group
Boca Raton London New York

CRC Press is an imprint of the
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CRC Press
Taylor & Francis Group
6000 Broken Sound Parkway NW, Suite 300
Boca Raton, FL 33487-2742

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Printed on acid-free paper

International Standard Book Number-13: 978-1-4987-8114-5 (Hardback)

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Library of Congress Cataloging-in-Publication Data

Names: Racz, LeeAnn, editor.
Title: Handbook of respiratory protection : safeguarding against current and emerging hazards/edited by LeeAnn Racz, Dirk P. Yamamoto, Robert M. Eninger.
Description: Boca Raton : Taylor & Francis, CRC Press, 2018. | Includes bibliographical references.
Identifiers: LCCN 2017032936 | ISBN 9781498781145 (hardback : alk. paper)
Subjects: LCSH: Breathing apparatus--Handbooks, manuals, etc. | Respirators--Handbooks, manuals, etc. | Respiratory organs--Diseases--Prevention--Handbooks, manuals, etc.
Classification: LCC T55.3.G3 H36 2018 | DDC 620.8/6--dc23
LC record available at https://lccn.loc.gov/2017032936

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Preface

Although respirators are ideally used as a last resort measure of protecting worker health, they continue to be critical tools in removing contaminants from breathed air. However, there have been many advances in respiratory protection policy and technology over the past decades. In addition, personal protective equipment has been required to evolve with the changing nature of occupational and environmental respiratory hazards. There are new hazards in health care, emergency response, manufacturing operations, maintenance activities, and other industries which have emerged over the years that have prompted research and development of advanced industrial hygiene and safety practices.

The *Handbook of Respiratory Protection: Safeguarding against Current and Emerging Hazards* provides a contemporary update and adjunct to previous texts on the subject, with a focus on the state of current understanding. Research in respiratory protection is cross-disciplinary, and contributions from many academic areas have expanded our current understanding of human factors and compliance, mask fit and comfort, and use of respiratory protection against health hazards that may not be completely understood. Therefore, authors from many disciplines have contributed to this handbook to provide a broader understanding of the multifaceted nature of today's respiratory protection.

The handbook opens with a section on the fundamentals of respiratory protection and the next covers various aspects of program management. Following a section on respirator fit, the handbook covers developments in respiratory protection for industry, health care and infectious disease, and emergency responders. Finally, we discuss emerging issues such as protection against nanoparticles, respirator modeling, and other research advancements.

The limits of industrial hygiene and safety professionals' conventional wisdom may be pushed as they attempt to provide respiratory protection for evolving hazards. These highly trained individuals must be aware of the latest advances in respiratory protection. This handbook provides guidance for protection during processes and scenarios only recently encountered as well as those long since in practice.

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Acknowledgments

We gratefully acknowledge the contributions and support of all those who played a part in the development of the manuscript for this book. Special thanks go to our families for their support and patience in this important endeavor to help protect the industrial workforce.

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Section I

Overview and Fundamentals

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1

An Overview of Respiratory Protection

Dirk P. Yamamoto and Robert M. Eninger

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> No one should have to sacrifice their life for their livelihood, because a nation built on the dignity of work must provide safe working conditions for its people.
>
> **Thomas E. Perez**
> *Former US Secretary of Labor*

1.1 Introduction

A respirator is a type of "personal protective equipment" (PPE) designed to protect an individual from harmful inhalational exposures, such as from chemicals and particulate matter. Under the traditional "hierarchy of controls," PPE is the "last resort," relied on only when material substitution, engineering control, and administrative control options have been exhausted. Respirators function by either physical removal of contaminants from the air being breathed or by supplying clean respirable air.

In the United States, an estimated 5 million workers are required to wear respirators in approximately 1.3 million workplaces (OSHA 2016). Selecting the right type of respiratory protection is driven by an exposure assessment, usually performed by an industrial hygienist or safety professional. The Occupational Safety and Health Administration (OSHA) regulates respiratory protection through 29 CFR 1910 Subpart I Personal Protective Equipment, under the standard 29 CFR 1910.134 Respiratory Protection. Other industries, such as those covered under Parts 1915 Shipyards, 1917 Marine Terminals, 1918 Longshoring, and 1926 Construction, defer to 1910.134 for respiratory protection purposes. Key elements of 1910.134 include requirements of a respiratory protection program, selection of respirators, medical evaluation, fit testing, use of respirators, maintenance/care of respirators, breathing air quality and use, filters/cartridges, training, program evaluation, and recordkeeping. Employer compliance remains a challenge, with the Respiratory Protection standard typically being a top 10 most frequently cited OSHA standard, year after year.

This text, the *Handbook of Respiratory Protection: Safeguarding against Current and Emerging Hazards*, contains 24 chapters organized in 7 major areas. It is intended to be a contemporary update and adjunct to previous texts on the subject, with a focus on the state of current understanding. Research in respiratory protection is cross-disciplinary, and contributions from many academic areas have expanded our current understanding of human factors and compliance, mask fit and comfort, and use of respiratory protection against health hazards that are or may not be completely understood, such as certain biological agents. By necessity, we have reached out to authors in many disciplines to gain a broader understanding of respiratory protection.

1.2 Handbook Organization

In Section I, Overview and Fundamentals, a basic overview is provided and respirator classification and types are reviewed. Additionally, two chapters focus on human factors aspects of respirator wear—spirometry and speech intelligibility. When worn, respirators may limit mobility, and can negatively impact productivity. In Chapter 5, speech intelligibility is insightful because verbal communication is a factor in potential unsafe conditions in workplaces that require teamwork and auditory communication.

In Section II, Program Management, several aspects and intricacies of respiratory protection programs are discussed. It is the editors' opinion that effective wear of respiratory protective equipment can only be sustained within the framework of an adequately managed program. Health and safety practitioners must take this into consideration as they apportion their time among multiple programs. In this section, elements of effective respiratory programs and factors that impact workplace implantation are discussed. An additional chapter is provided on using novel social media approaches to promote effective respiratory program equipment (RPE) use. Additionally, a case study on RPE program management in academic settings is provided, although there are observations that are generalizable to other industries.

Section III, Respirator Fit, begins with a chapter reviewing respirator fit testing. There are few elements as important in an effective RPE program than assessing respirator fit on the individual who will be using it in the workplace. This critical task is not only to assure fit in a test-setting, but also serves to train the individual user on putting the RPE on and taking it off, among other responsibilities. This is a useful and concise chapter to review these basic principles if the reader is returning to this area of health and safety practice. The other two chapters from this section focus on more nuanced technical observations of respirator fit, and particle penetration through both filters and small leaks. Over the last 15 years, our understanding has significantly increased of the role of two pathways for particle penetration in RPE devices. Our understanding of the ratio of penetration from leakage as compared to filter penetration underscores the importance of RPE that fits well and suits a variety of face shapes and sizes.

Section IV, Respiratory Protection for Industry, dives into two specific areas of relevance to health and safety practitioners: isocyanate exposures and developing RPE protection provided by activated carbon fibers. Isocyanates are substances which can cause sensitization by both the respiratory and dermal route. At the same time, substances which use isocyanates have wide use in industry. Although this chapter focuses on RPE to protect against isocyanate exposure in autobody repair and refinishing, there are useful observations which may be applied to other industries. As the most common adsorbent used in chemical cartridges employed on respirators is granulated activated carbon, the next chapter reviews breakthrough curves of different activated carbon fiber formulations when challenged with toluene. Activated carbon fibers are a novel approach to respirator cartridges. The reader may note that this chapter provides insight into the technical behavior of adsorbent behavior in general. The same principles which govern removal of chemicals in a respirator cartridge also apply to chemical air sampling into an adsorbent tube.

Section V focuses on RPE for healthcare and infectious disease protection. This has been an area of intensive research for over a decade. Healthcare and infectious disease are one of the few settings that protective masks may be worn to protect against not only respiratory exposure (what is breathed in), but also what may be expired, coughed, splattered, etc, that may possess infectious materials. It is a very complex environment that deserves the critical attention and awareness of health and safety practitioners. The first chapter in this section discusses an evaluation of facemasks and respirators to avert infection in a community environment. As facemasks and respirators must comply with different regulatory and testing requirements, this chapter is enlightening for generalist practitioners to help them understand differences in workplace performance and employment. The next chapter summarizes a unique study which utilized a cough simulator to test the effectiveness of face shields in protecting against expired particles. It is a useful study that illustrates some of the physical aspects of potential infectious particle generation in a healthcare setting.

In Section VI, Respiratory Protection for Emergency Responders, three chapters discuss RPE for specific worker populations. The first chapter looks at medical responders and receivers. It is important to note the differences in workplace stressors faced by medical first responders as compared to the healthcare environment, as addressed in Section V. Additionally, a chapter discusses RPE for firefighters during certain operations that may have high chemical and particle exposures. The authors utilized chemical, biological, radiological, and nuclear (CBRN) canisters to evaluate their possible use by firefighters. Firefighters have very complex exposure profiles and this study provides insight into alternative protection methods being evaluated for their use.

Section VII, Emerging Issues for Respiratory Protection, presents four chapters. The first addresses RPE against nanoparticles, which has been an area of substantial interest among researchers for some time. Nanomaterials may have unique or different toxicity than the same substance in bulk form, and this chapter addresses how RPE protects against this emerging hazard. The next chapter provides a contribution to our understanding of how to model respiratory protection, and asserts that the beta distribution is more appropriate than the lognormal distribution. Modeling RPE program effectiveness can be a technique used by epidemiology researchers who lack data about past exposures to populations who wore respiratory protection. This chapter is a useful contribution to our understanding of the topic. Next is a chapter that presents an approach to rapidly evaluate candidate activated carbon adsorbents. The proposed method aims to assist manufacturers of respiratory protection in considering differing activated carbon formulations for use in RPE. This provides insight into some of the development considerations that go into RPE design and manufacturing. Last in Section VII is an overview of a wide range of respiratory protection research in the United States Air Force. The USAF has over 21,000 employees enrolled in respiratory protection programs at a given time and uses RPE against a very wide variety of hazards. This chapter summarizes research and discovery activities on both civil and military-specific protective masks.

1.3 Summary

To summarize, this text is a wide-ranging attempt to capture contemporary RPE knowledge and to highlight emerging issues across a range of applications. It touches on the basics and applies practical as well as highly technical (and some theoretical) aspects of respiratory protection. This book should serve as an update in some technical areas and an adjunct in other areas to previous texts on the topic. It has material appropriate for both general safety and health practitioners as well as researchers in one of several academic disciplines.

The editors wish to thank each of the contributors. Without their efforts this book would not have been possible.

Reference

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Types of Respirators

Dirk P. Yamamoto

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2.1 Employer Responsibilities

The current Occupational Safety and Health Administration (OSHA) Respiratory Protection standard, 29 CFR 1910.134, went into effect on April 8, 1998, and replaced the original 1971 version. By design, the Respiratory Protection standard specifies only the minimum requirements for an effective respiratory protection standard (OSHA 2011). As written in 29 CFR 1910.134(d), the employer is required to evaluate respiratory hazards in the workplace, including identifying the contaminant chemical state and physical form, along with evaluating employee exposure. If unable to do so, the employer must consider the atmosphere to be "immediately dangerous to life and health" (IDLH), which will drive more stringent respiratory protection requirements.

To evaluate employee exposure, the industrial hygienist or safety professional will perform an exposure assessment, which often includes air sampling to quantify exposure to airborne dusts, fumes, mists, gases, vapors, or smoke. The resulting concentration of each contaminant is then compared to an appropriate exposure limit (e.g., OSHA permissible exposure limit [PEL], American Conference of Governmental Industrial Hygienists [ACGIH] threshold limit value–time-weighted average [TLV–TWA], etc.) to help determine the level of protection necessary, for example, half-mask, full-facepiece, or supplied air respirator, etc. The physical state of the contaminant determines whether a filter or chemical cartridge is necessary to remove contaminants from inhaled air.

In general, the employer must identify all relevant workplace and user factors in order to select the proper respirator. Examples of workplace and user factors include the nature of the airborne hazard, concentration of the exposure, exposure limit, and type of work being performed. The type of work is an important consideration as it may preclude the use of certain respirator types. For example, industrial processes such as bead blasting to remove paint and corrosion from metal parts may warrant use of special respirators which incorporate hoods and helmets, providing protection from both dust and impact from the blast media.

Industrial hygiene and safety professionals traditionally follow a "hierarchy of controls" to protect the health of workers. This hierarchy is generally summarized, in order of priority, as: (1) elimination or substitution of the hazard, (2) engineering controls, (3) administrative controls, and (4) personal protective equipment (PPE). Following this hierarchy, exposures to harmful agents should be accomplished as much as is feasible by altering work processes, finding less toxic materials, and implementing engineering control measures such as enclosures, confinement, and general or local ventilation. When such controls are not feasible, or do not adequately control hazards, remaining inhalational exposures are controlled using appropriate respiratory protection in accordance with 29 CFR 1910.134. Note that PPE, including respirators, is regarded as the "last resort" as it may not be as reliable as more permanent control methods and, therefore, is not the preferred solution to reduce exposures to workers below exposure limits. Respirators can fail to adequately protect the wearer due to various issues such as spent respirator cartridges, poor fit, or human error which otherwise affects respirator performance.

Employers must select and provide, at no cost to the employee, the appropriate respirators based on the factors mentioned previously. A written respiratory protection program, which includes the procedures for selecting respirators, medical evaluations, fit testing, emergency situations, cleaning, storing, and training is also required (OSHA 2015). Further, employees should be provided a sufficient number of respirator models and sizes so that a respirator which is acceptable and correctly fits can be chosen during the fit-testing process. Note that all tight-fitting respirators require fit testing. See Chapter 11 for more details on fit testing and the OSHA fit test protocols.

2.2 Terminology Related to Inhalational Hazards

Important to the discussion of respiratory protection is an understanding of the terminology used to describe inhalational hazards. *Vapors* are the gaseous form of substances that are normally in the solid or liquid state at room temperature and pressure and are formed by evaporation (OSHA 2015). Solvents often produce vapors, for example, toluene and methylene chloride. *Gases* exist as individual molecules in the air at room temperatures (OSHA 2009). Examples include welding gases, carbon monoxide, oxygen, and nitrogen. *Aerosols* is a broadly used term to represent several two-phased systems comprised of a suspension of liquid or solid particles in a gas, usually air (Hinds 1999), with any solid particle portions being often referred to as "particulate matter" or PM (OSHA 2015). Listed below is a summary of other common airborne hazards (OSHA 2009):

- *Dusts*: Solid particles formed or generated from solid materials through mechanical processes such as crushing, grinding, drilling, abrading, or blasting. Examples: lead and silica dusts.
- *Fumes*: Solid particles formed when a metal or other solid vaporizes and the molecules condense or solidify in cool air. Examples: metal fumes from smelting or welding, fumes from plastic injection or injection molding processes.
- *Mists*: Tiny droplets of liquid suspended in air. Often generated by condensation during the transformation from the gaseous to the liquid state or by splashing, foaming, or atomizing. Examples: oil mist from metal cutting processes, acid mists from electroplating, and paint spray mist.
- *Smoke*: Carbon or soot particles from incomplete combustion of carbon-based materials such as coal or oil. Often contains droplets (liquid), along with dry particles.

2.3 NIOSH-Approved Respirators

In the United States, respirators are tested under the authorization of the Occupational Safety and Health Act of 1970. Specifically, the National Institute of Occupational Safety and Health (NIOSH), through its NIOSH National Personal Protective Technology Laboratory (NPPTL), provides testing, approval, and a certification program to help ensure respirators meet the test criteria of 42 CFR 84 Approval of Respiratory Protective Devices (NIOSH 2017). In 1995, 42 CFR 84 replaced 30 CFR 11 for certification requirements for respiratory protective devices. With implementation of 42 CFR 84, NIOSH was given exclusive authority for testing and certification of respirators with few exceptions for emergency devices for the mining industry (NIOSH 2017).

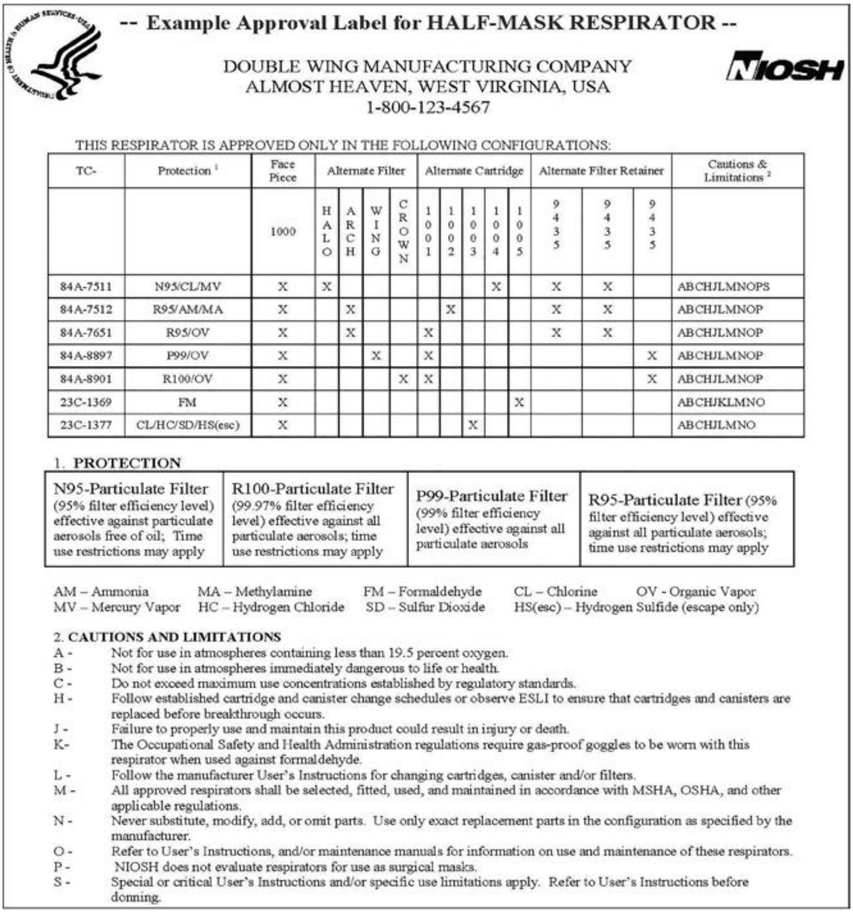
Approved respirators are assigned a "testing and certification" (TC) approval numbers by NIOSH and are granted certificates of approval. These are issued for entire respirators and not for individual respirator components (NIOSH 2011). Usually the approval number does not appear on the respirator itself, but on a separate NIOSH approval label either on or within the packaging for the respirator. A full NIOSH approval label for the respirators is to be provided with the facepiece and one for each air-purifying component which is part of the certificate of approval. Such a label contains the NIOSH emblem, manufacturer information, approval number, cautions/limitations, and unique configurations which are approved (NIOSH 2011). These labels are typically printed on paper. An example of a NIOSH approval label is shown in Figure 2.1 (NIOSH 2011). Approval labels provide essential information to also determine whether a respirator is configured in a manner consistent with its NIOSH certificate of approval. Use of respirator components not part of the approval label and, therefore, not part of the certificate of approval, can cause serious injury and/or death to the wearer (NIOSH 2011).

Individual respirator cartridges and filters typically have *abbreviated* labels instead of full approval labels. These abbreviated versions contain the NIOSH emblem, protection, manufacturer part number, and lot number. They are either affixed as an adhesive label or are printed directly on the device (NIOSH 2011). For filtering facepieces in which the complete respirator is the filter, the abbreviated label information is often printed directly onto the facepiece. See Figure 2.2.

If approved, these respirators (i.e., manufacturer, make, and model) appear in the NIOSH-Certified Equipment List (CEL) which is available to employers, employees, safety/health personnel, etc., at the NPPTL webpage (NIOSH 2017). The NIOSH CEL is searchable by approval number, manufacturer, respirator type, etc. The list can be used by employers to identify potential respirator solutions and to verify that a given respirator is NIOSH-approved. This is important as not all respirators sold commercially are NIOSH-approved respirators. In addition, there have been incidents of counterfeit respirators bearing realistic labeling and/or approval numbers. On rare occasion, respirator approvals are revoked by NIOSH and employers should use the CEL to verify the status of respirators in their inventory.

2.4 Filters

The various classes of NIOSH-approved particulate respirators are based on the amount of filtration provided (i.e., 95%, 99%, and 100%) and the filter's resistance to oil which is determined using laboratory testing. There are



-- Example Approval Label for HALF-MASK RESPIRATOR --

DOUBLE WING MANUFACTURING COMPANY
ALMOST HEAVEN, WEST VIRGINIA, USA
1-800-123-4567

THIS RESPIRATOR IS APPROVED ONLY IN THE FOLLOWING CONFIGURATIONS:

TC-	Protection [1]	Face Piece	Alternate Filter				Alternate Cartridge					Alternate Filter Retainer			Cautions & Limitations [2]
		1000	HALO	ARCH	WING	CROWN	1001	1002	1003	1004	1005	9435	9435	9435	
84A-7511	N95/CL/MV	X	X							X		X	X		ABCHJLMNOPS
84A-7512	R95/AM/MA	X		X				X				X	X		ABCHJLMNOP
84A-7651	R95/OV	X		X			X					X	X		ABCHJLMNOP
84A-8897	P99/OV	X			X		X							X	ABCHJLMNOP
84A-8901	R100/OV	X				X	X							X	ABCHJLMNOP
23C-1369	FM	X									X				ABCHJKLMNO
23C-1377	CL/HC/SD/HS(esc)	X							X						ABCHJLMNO

1. **PROTECTION**

N95-Particulate Filter	R100-Particulate Filter	P99-Particulate Filter	R95-Particulate Filter
(95% filter efficiency level) effective against particulate aerosols free of oil; Time use restrictions may apply	(99.97% filter efficiency level) effective against all particulate aerosols; time use restrictions may apply	(99% filter efficiency level) effective against all particulate aerosols	(95% filter efficiency level) effective against all particulate aerosols; time use restrictions may apply

AM – Ammonia
MA – Methylamine
FM – Formaldehyde
CL – Chlorine
OV - Organic Vapor
MV – Mercury Vapor
HC – Hydrogen Chloride
SD – Sulfur Dioxide
HS(esc) – Hydrogen Sulfide (escape only)

2. **CAUTIONS AND LIMITATIONS**

A - Not for use in atmospheres containing less than 19.5 percent oxygen.
B - Not for use in atmospheres immediately dangerous to life or health.
C - Do not exceed maximum use concentrations established by regulatory standards.
H - Follow established cartridge and canister change schedules or observe ESLI to ensure that cartridges and canisters are replaced before breakthrough occurs.
J - Failure to properly use and maintain this product could result in injury or death.
K- The Occupational Safety and Health Administration regulations require gas-proof goggles to be worn with this respirator when used against formaldehyde.
L - Follow the manufacturer User's Instructions for changing cartridges, canister and/or filters.
M - All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA, and other applicable regulations.
N - Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.
O - Refer to User's Instructions, and/or maintenance manuals for information on use and maintenance of these respirators.
P - NIOSH does not evaluate respirators for use as surgical masks.
S - Special or critical User's Instructions and/or specific use limitations apply. Refer to User's Instructions before donning.

FIGURE 2.1
Example of a NIOSH approval label for a half-mask respirator. (Courtesy of the National Institute for Occupational Safety and Health (NIOSH). 2011. *NIOSH Approval Labels-Key Information to Protect Yourself*. Department of Health and Human Services (NIOSH) Publication No. 2011–179. Available at (https://www.cdc.gov/niosh/docs/2011-179/pdfs/2011-179.pdf. Accessed June 3, 2017.)

seven primary NIOSH-approved classes as described in Table 2.1 (NIOSH 2017). Oil resistance is an important factor as the presence of oil as an aerosol can compromise filtration. The letter prefix of N, P, and R of the respirator class refers to the filter's ability to protect against oil aerosols. N-series filters are *non-oil proof* (i.e., somewhat resistant) and are not intended for solid or liquid airborne particulate containing oil aerosols. If mineral, vegetable, synthetic oil, or other oily material is present in the air, then an R- or P-series filter is required. R-series filters are *partially resistant* to oil aerosols, but can only be used for a limited duration in an oil aerosol environment. P-series filters are considered *oil proof*, perhaps better described as being "strongly

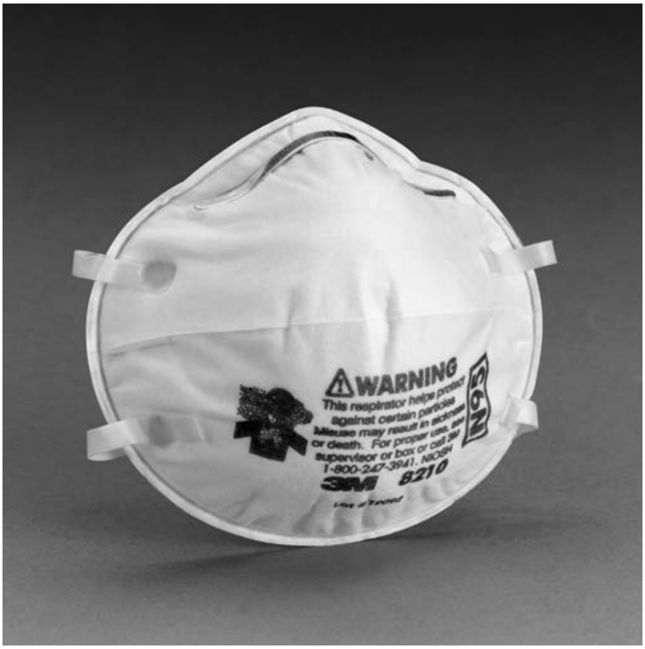


FIGURE 2.2
An N95 respirator with an abbreviated NIOSH approval label printed onto the facepiece. (Courtesy of 3M.)

resistant," and provide the best protection against oil aerosols. These P-series filters still require time-use limitations, however. Generally, P-series filters can be used longer than R-series for a given exposure level.

Note also that particulate filters are color-coded with a fair amount of standardization across manufacturers through reliance on the American National Standards Institute (ANSI) standard K-13-1973, which is called out in 42 CFR 84. It has since been replaced by the Z88.7 standard, which was most recently updated in 2010 and was retitled as ANSI/AIHA/ASSE Z88.7-2010 Color Coding of Air Purifying Respirator Canisters, Cartridges, and Filters. An example of standardization is P100 particulate filters being constructed with easy-to-identify purple or magenta labels or materials, even across different manufacturers.

2.5 Chemical Cartridges

Respirator *cartridges* are containers with sorbent or catalyst material, or a combination, which remove or detoxify a specific contaminant or class of contaminants. Respirator *canisters* are similar to cartridges, except they

TABLE 2.1

Seven Primary NIOSH Respirator Filter Classes

Filter Class	Oil Mist Resistance	Filter Efficiency[a]
N95[b]	Not resistant to oil	Filters at least 95% of airborne particles. For any solid or liquid airborne particulates free of oil aerosols.
N99	Not resistant to oil	Filters at least 99% of airborne particles. For any solid or liquid airborne particulates free of oil aerosols.
N100	Not resistant to oil	Filters at least 99.97% of airborne particles. For any solid or liquid airborne particulates free of oil aerosols.
R95	Somewhat resistant to oil	Filters at least 95% of airborne particles. For any solid or liquid airborne particulates, but is only somewhat resistant to oil aerosols.
P95	Strongly resistant to oil	Filters at least 95% of airborne particles. For any solid or liquid airborne particulates and is strongly resistant to oil aerosols.
P99	Strongly resistant to oil	Filters at least 99% of airborne particles. For any solid or liquid airborne particulates and is strongly resistant to oil aerosols.
P100	Strongly resistant to oil	Filters at least 99.97% of airborne particles. For any solid or liquid airborne particulates and is strongly resistant to oil aerosols.

[a] Actual testing performed using the most penetrating aerosol size of ~0.3 μm aerodynamic mass median diameter, with sodium chloride (NaCl) as the aerosol for N-series and dioctylphthalate (DOP) for R- and P-series. (3M. 2015b. 3M Respirator Selection Guide. Available at http://multimedia.3m.com/mws/media/639110O/3m-respirator-selection-guide.pdf. Accessed June 3, 2017.)

[b] Surgical N95 FFRs: NIOSH-approved surgical N95 respirators have also been cleared by the FDA as medical devices. Note that only a subset of N95 FFRs have this distinction.

are simply larger in volume. Contaminants protected against by respirator cartridges/canisters are in gaseous or vapor form. Sorbents are usually made of porous media, serving to physically remove contaminants typically through an adsorption mechanism. Conversely, catalyst materials serve to chemically react with contaminants to render them less toxic (Colton 2011). Chemical cartridges can protect against contaminants such as organic vapors, chlorine gas, carbon monoxide, pesticides, ammonia gas, etc., along with certain combinations of contaminants. The selection of cartridges available varies between respirator manufacturers. Similar to particulate filters, manufacturers of chemical cartridges follow a common convention, through use of standards such as ANSI K-13-1973 or ANSI/AIHA/ASSE Z88.7-2010, for color-coding of labels used to differentiate respirator cartridges, for example, black = organic vapor, white = acid gas, green = ammonia gas, etc.

These removal mechanisms remain very efficient until sorbent capacity is exhausted or the catalyst is poisoned, after which "breakthrough" of contaminant occurs (Colton 2011). To help prevent breakthrough conditions, OSHA requires that employers provide either an atmosphere-supplying respirator or an air-purifying respirator equipped with (1) an end-of-service-life indicator (ESLI) certified by NIOSH for the contaminant or (2) a changeout schedule for canisters/cartridges that is, based on objective data to ensure canisters and cartridges are changed before the end of their service life (OSHA 1998). ESLIs should be used when available and appropriate for the workplace. If no ESLI is available, the employer must develop a respirator cartridge changeout schedule based on available data that describe the service life of the sorbent. To date, there are very few NIOSH-approved ESLIs for respirator cartridges and canisters, thus employers are more likely to have to rely on establishing appropriate changeout schedules (OSHA 2011).

An ESLI is a system designed to warn the user that a respirator is near the end of adequate respiratory protection, such as when the cartridge sorbent material is approaching saturation or is no longer being effective (OSHA 2011). An ESLI is used only for chemical cartridges, not particulate-removing filters. For particulate-removing filters, workers should be trained to change out the filters when difficulty breathing through the filter is experienced, most likely due to excessive loading of particulates onto the filter (OSHA 2011). A more frequent changeout schedule for particulate-removing filters is recommended, however.

An example of an ESLI is the 3M™ Service Life Indicator, which appears on the side of some 3M respirator cartridges and is used for certain organic vapors and exposure concentrations (3M 2015a). A protective tab shields the indicator and can be peeled back to periodically check the ESLI. When the visual indicator bar reaches the end-of-service line, then the cartridge should be changed out. As a best practice, an ESLI should be used in conjunction with a cartridge changeout schedule.

In the absence of respirator cartridges equipped with ESLIs, a changeout schedule must be used. Such schedules should be developed by a qualified professional such as an industrial hygienist, safety professional, or researchers specializing in respiratory protection. Essentially, the changeout schedule must result in replacing cartridges before the service life of the old ones is depleted (i.e., sorbent capacity is exhausted) under the work conditions experienced by the wearer.

Relying on the worker's ability to sense the odor of the gas or vapor as the primary means to detect contaminant breakthrough is not permitted by OSHA. But, odor detection can be used as a secondary or backup indicator for changing out cartridges (3M 2015b). Published values for odor thresholds of common chemicals are available and are most useful when significantly below exposure limits in order to provide a margin of safety. For chemicals with poor warning properties, there will be no secondary indicator of when to change out cartridges, thus warranting consideration of a more conservative changeout schedule or use of atmosphere-supplying respirators.

Respirator manufacturers also provide "combination cartridges," such as a combined aerosol filter/organic vapor or aerosol filter/organic vapor/acid gas cartridge. Many combinations are available and are useful when exposures to multiple hazard types occur simultaneously. Availability differs between manufacturers and care must be used to identify the right combination cartridge for the given airborne hazards.

2.6 Assigned Protection Factors

As written in 29 CFR 1910.134(b), the assigned protection factor (APF) is the "workplace level of respiratory protection that a respirator or class of respirators is expected to provide to employees when the employer implements a continuing, effective respiratory protection program" (OSHA 2009). The employer uses the OSHA APFs (Table 2.2) to select a respirator that meets or exceeds the level of protection necessary.

Mathematically, the employer calculates the concentration of the contaminant in air divided by the occupational exposure limit, for example, OSHA PEL, ACGIH TLV–TWA, German MAK (maximale Arbeitsplatz-Konzentration), or similar Equation 2.1. An APF at least equal to, if not greater, than the calculated value must be chosen.

$$\mathrm{APF} \geq \frac{C_{\mathrm{air}}}{\mathrm{OEL}} \tag{2.1}$$

where:

APF = assigned protection factor

C_{air} = concentration of the contaminant in air, in mg/m^3 or ppm

OEL = occupational exposure limit, in mg/m^3 or ppm

2.7 Maximum Use Concentration

The maximum use concentration (MUC) is defined as the maximum atmospheric concentration of a hazardous substance for which an employee can

TABLE 2.2

Assigned Protection Factors[a]

Type of Respirator[b,c]	Half-Mask	Full-Facepiece	Helmet/Hood	Loose-Fitting Facepiece
APR	10[d]	50	–	–
PAPR	50	1000	25/1000[e]	25
SAR or airline respirator				
Demand mode	10	50	–	–
Continuous flow mode	50	1000	25/1000[e]	25
Pressure-demand or other positive-pressure mode	50	1000	–	–
SCBA				
Demand mode	10	50	50	–
Pressure-demand or other positive-pressure mode (e.g., open/closed circuit)	–	10,000	10,000	–

Note: Adapted from Occupational Safety and Health Administration (OSHA). 1998. Respiratory Protection, 29 CFR 1910.134, Final Rule. *Federal Register Notice*.

[a] These APFs do not apply to respirators used solely for escape. For escape respirators used in association with specific substances covered by 29 CFR 1910 Subpart Z, employers must refer to the appropriate substance-specific standards in that subpart. Escape respirators for other IDLH atmospheres are specified by 29 CFR 1910.134(d)(2)(ii).

[b] Employers may select respirators assigned for use in higher workplace concentrations of a hazardous substance for use at lower concentrations of that substance, or when required respirator use is independent of concentration.

[c] The APFs are only effective when the employer implements a continuing, effective respirator program as required by this section (29 CFR 1910.134), including training, fit testing, maintenance, and use requirements.

[d] The APF category includes filtering facepieces and half-masks with elastomeric facepieces.

[e] The employer must have evidence provided by the respirator manufacturer that testing of these respirators demonstrates performance at a level of protection of 1000 or greater to receive an APF of 1000. This level of performance can best be demonstrated by performing a workplace protection factor (WPF) or simulated workplace protection factor (SWPF) study or equivalent testing. Absent such testing, all other PAPRs and SARs with helmets/hoods are to be treated as loose-fitting facepiece respirators, and receive an APF of 25.

be expected to be protected when wearing a respirator (OSHA 2009) and is the upper limit for which a class of respirators is expected to provide protection. Simply stated, employers must select a respirator for the employee that maintains the exposure (measured outside the respirator) at or below the MUC (OSHA 1998). MUC is a rearrangement of Equation 2.1 and is determined mathematically by multiplying the APF by the occupational exposure limit (OEL). See Equation 2.2. Further, the employer should not apply the MUC to conditions deemed immediately dangerous to life or health (IDLH). Instead, the only respirators approved for IDLH conditions are full-facepiece pressure demand SCBA certified by NIOSH for a minimum service life of 30 minutes or a combination full-facepiece pressure demand supplied air respirator with auxiliary self-contained air supply as specified in 29 CFR 1910.134(d)(2) (OSHA 1998).

$$\mathrm{MUC} = \mathrm{APF} \times \mathrm{PEL} \tag{2.2}$$

MUC = maximum use concentration, in milligrams per cubic meter (mg/m^3) or parts per million (ppm)

APF = assigned protection factor

PEL = permissible exposure limit, in mg/m^3 or ppm

2.8 Respirator Classifications

2.8.1 Overview

Respirators protect the wearer by either removing contaminants from air before being inhaled or by providing a supply of clean, respirable air. These are referred to as "air purifying" and "atmosphere-supplying" respirators, respectively (OSHA 2017). Both classes can be divided into "tight-fitting" and "loose-fitting" facepieces, referring to the seal between respirator and the face. For tight-fitting facepieces, the employer must provide the employee a respirator that gives a good facepiece-to-face seal, as indicated by a "fit test." See Chapter 11 for details on qualitative and quantitative fit-testing.

Tight-fitting facepieces are also categorized as being either (1) "half-face" (half-mask), covering primarily the mouth, nose, and surrounding facial area or (2) "full-face" (full-facepiece), covering the mouth, nose, eyes, and surrounding facial area. Tight-fitting facepieces will not provide adequate respiratory protection if they fit poorly, as even tiny air leaks between the facepiece-to-face seal can greatly compromise protection.

Loose-fitting respirators are typically hood- or helmet-style respirators that fit over the entire head and form only a partial seal with the face. They typically include a neck seal that does not require a careful fit to help ensure respiratory protection. As they are not tight-fitting, they do not require fit testing. Hooded respirators can also cover portions of the shoulders and torso. These hoods can be either disposable or reusable and are made of such materials as Tyvek®, polyethylene, or polypropylene. Hooded respirators are advantageous for industrial work with potential splash hazards. Similarly, air supplied helmets are designed to protect the head against top impact and penetration hazards. They are commonly used in processes involving grinding, sanding, painting, and media blasting.

Further, respirators can be either negative or positive pressure, which refers to the air pressure within the facepiece during inhalation, with respect to ambient air. Negative pressure respirators are most common and rely on human inhalation to breathe air through a filter or a cartridge. Examples include filtering facepiece, half-mask, and full-facepiece respirators. Positive pressure respirators (air pressure inside the mask greater than ambient air pressure) can be advantageous as they can help prevent against contaminants leaking into the respirator due to a poor facepiece-to-face seal.

2.8.2 Air-Purifying Respirators

An air-purifying respirator (APR) is "a respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element" (OSHA 2009). APRs are designed to remove particulates, gases/vapors, or a combination of the two. Filters are used to remove particulates, while chemical cartridges (canisters) are used for gas and vapor removal. Combination cartridges stack both a filter and chemical cartridge together to provide removal of particulates and gases/vapors, alike.

2.8.2.1 Elastomeric Respirators

Half-mask and full-facepiece elastomeric respirators have molded facepieces made of natural or synthetic elastic material, including natural rubber, silicone, or ethylene propylene diene monomer (EPDM) rubber (OSHA 2009) (Figure 2.3). Half-mask respirators are designed to cover the chin to the bridge of the nose from underneath, while full-facepiece respirators extend to near the hairline above the eyes. Full-facepiece respirators provide greater protection than half-mask respirators, especially as they are more difficult to dislodge due to their greater surface contact between facepiece and face. An additional benefit is that they provide eye protection, such as in very dusty environments.

Each respirator manufacturer designs its own facepieces in multiple sizes to fit various sizes and shapes of faces. An important part of an employer's respiratory protection program is ensuring that multiple makes/models/sizes of respirators are available for employees to choose from, in order to accommodate various sized/shaped faces.

2.8.2.2 Filtering Facepiece Respirators

Filtering facepiece respirators (FFRs) are negative pressure respirators with the filter as an integral part of the facepiece (e.g., valved N95s) or with the entire facepiece constructed of the filtering medium. See Figure 2.4 for an example of a valved N95 FFR. They provide an affordable, lightweight, and often more comfortable respiratory protection solution for exposures at or below 10 times the OSHA PEL (i.e., APF = 10), as they are considered half-mask respirators. FFRs are considered to be disposable respirators and help protect against most particulates. However, they do not protect against gases, vapors, or spray, and provide only minimal protection against direct liquid splashes (NIOSH 2013). They cannot be cleaned, disinfected, or have their filter replaced after use. The most common type of filtering facepiece is

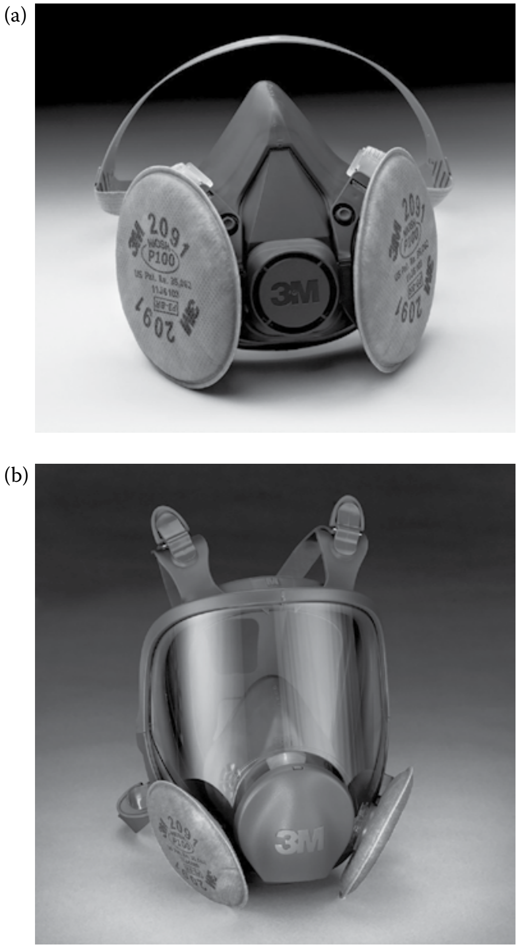


FIGURE 2.3
Examples of elastomeric respirators. (a) Half-mask respirator, (b) Full-facepiece respirator. (Courtesy of 3M.)

the "N95 respirator," or N95 FFR, which provides 95% filter efficiency when tested against a 0.3 μm sodium chloride (NaCl) aerosol.

FFRs often have the NIOSH approval numbers shown on the filter material itself, which is different from other respirators which usually have a separate NIOSH approval label located on or within the respirator's packaging. FFRs, like other tight-fitting respirators, need to be fit-tested to the worker. A thorough discussion of fit testing is in Chapter 11.

The N95 FFR is perhaps the most commonly used respirator in healthcare and is typically used to avoid the spread of infectious disease. Traditional "surgical masks" are not NIOSH-approved respirators and primarily

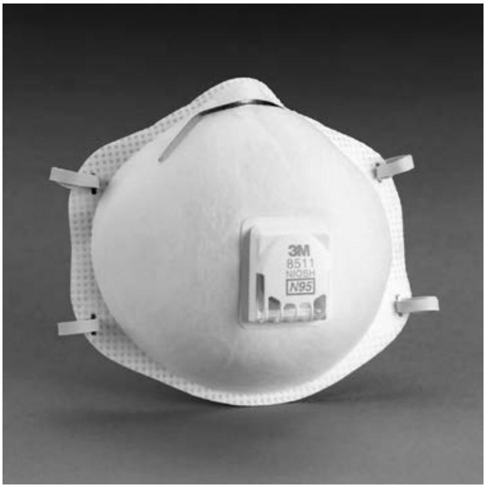


FIGURE 2.4
Example of an N95 FFR. This is a valved N95 designed to help reduce buildup of heat and moisture inside the facepiece. (Courtesy of 3M.)

serve to protect patients from saliva and respiratory secretions from the healthcare worker. These surgical masks provide only minimal protection against large droplets, splashes, sprays, or splatter (NIOSH 2013). They do not effectively filter small particles and are not designed to prevent leakage around the edge of the mask during inhalation (NIOSH 2017). However, a subset of N95 FFRs are approved for medical or surgery-related purposes as not only are they NIOSH-approved respirators, but are also cleared by the Food and Drug Administration (FDA) as medical devices. Note that only a small subset of N95 respirators have the distinction of dual approvals by both NIOSH and FDA and they are commonly referred to as "surgical N95" respirators.

2.8.2.3 Powered Air-Purifying Respirators

A powered air-purifying respirator (PAPR) is an APR that relies on a mechanical blower to force ambient air through air-purifying elements to the facepiece of the respirator (Figure 2.5). PAPRs can be used with half-mask, full-facepiece, or hoods. Because of the mechanical blower, PAPRs help reduce the amount of work required by the user, thus potentially increasing worker comfort and productivity. However, PAPRs are not suitable for oxygen-deficient atmospheres, as they only purify ambient air and do not supply the necessary breathing-quality air. Further, if entering an unknown atmosphere, for example, unknown contaminants at unknown concentrations, then an atmosphere-supplying respirator should be used and not a PAPR.

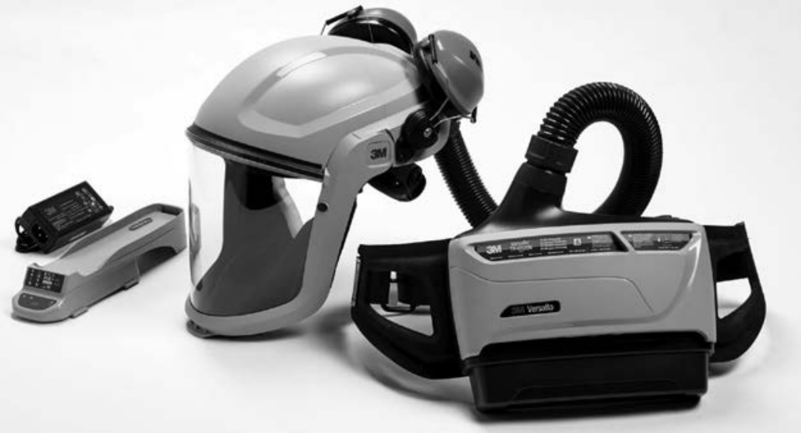


FIGURE 2.5
Example of a PAPR. (Courtesy of 3M.)

2.8.3 Atmosphere-Supplying Respirators

Atmosphere-supplying respirators are generally used in high-hazard environments and provide a clean source of respirable air instead of removing particulates or gases/vapors from existing air via filters or chemical cartridges. They are used when air purifying respirators cannot provide adequate protection for high airborne concentrations of chemicals, oxygen deficient and unknown atmospheres, and other immediately dangerous to life and health (IDLH) conditions. For atmosphere-supplying respirators, special air compressors capture air from the surrounding environment, filter it, remove oil (if any), then compress it for delivery or storage purposes. Atmosphere-supplying respirators are classified into two general types: supplied-air respirators (SARs) and self-contained breathing apparatus (SCBA). Regardless of the type, pressuring-reducing regulators are used on the compressed air to deliver an appropriate breathable pressure for the respirator user (OSHA 2011).

All oxygen-deficient atmospheres, defined as less than 19.5% O_2 by volume, are considered IDLH by OSHA, with an exception for when an employer can demonstrate that the oxygen concentration can be maintained within the ranges in Table 2.3 below. If that can be done, then any atmosphere-supplying respirator may be used (OSHA 1998).

Atmosphere-supplying respirators are designed to be continuous flow, demand, or pressure demand. Continuous flow ASRs provide a continuous flow of breathing air to the facepiece (positive pressure). Demand ASRs are negative pressure respirators and are useful when relying on a large compressed air cylinder of breathable air or a bank of such cylinders connected in a cascading fashion (OSHA 2011). Pressure demand ASRs provide a positive pressure environment within the facepiece and breathing air is supplied only when a pressure differential (demand) is created as the wearer inhales.

TABLE 2.3

Oxygen-Deficient Atmospheres Which the Employer May Rely on Atmosphere-Supplying Respirators

Altitude (feet)	O_2 (%)
Less than 3001	16.0–19.5
3001–4000	16.4–19.5
4001–5000	17.1–19.5
5001–6000	17.8–19.5
6001–7000	18.5–19.5
7001–8000[a]	19.3–19.5

[a] Above 8000 feet, the exception does not apply. Oxygen-enriched breathing air must be supplied above 14,000 feet.

Per 29 CFR 1910.134(i), compressed breathing air used for atmosphere-supplying respirators must at least meet the requirements of the ANSI/Compressed Gas Association (CGA) specifications for Grade D breathing air, including oxygen content and limits for certain contaminants. Key requirements of compressed breathing air include

- Oxygen content must be between 19.5% and 23.5% (volume per volume)
- Hydrocarbon (condensed): ≤ 5 mg/m^3
- Carbon monoxide (CO): ≤ 10 ppm
- Carbon dioxide (CO_2): ≤ 1000 ppm
- Lack of noticeable odor

Historically, a common cause of fatalities among workers using airline respirators was inadvertent connection of airline respirators with non-respirable gases. To prevent this, 29 CFR 1910.134(i)(8) and the ANSI/ASSE Z88.2 standards specify that respirator airline couplings must be incompatible with those for other gas systems to prevent purposeful or accidental connections that can lead to serious injuries or death (OSHA 1998, ANSI/ASSE 2015). These accidental connections include attaching airline respirators to compressed air systems that are not Grade D certified (i.e., not breathable), including lines that may contain harmful levels of other gases. These other gases, especially when they lack adequate warning properties, can lead to injury or death.

2.8.3.1 Supplied-Air Respirators

SARs, also known as airline respirators, receive air through a hose connected to a dedicated air supply, such as an air compressor or pressurized cylinder (OSHA 2011). These can be configured as continuous flow (continuous positive pressure), demand (uses a tight-fitting facepiece and undergoes negative pressure during inhalation), or pressure demand (tight-fitting facepiece and is normally under positive pressure after inhalation). Continuous flow SARs are normally under positive pressure. Demand SARs are normally under negative pressure during inhalation and rely on tight-fitting facepieces. Pressure demand SARs are normally under positive pressure and also require a tight-fitting facepiece.

2.8.3.2 Self-Contained Breathing Apparatus

As implied by the name, the SCBA is designed so that cylinders carried by the user provide the breathing air and thus become suitable for unknown atmospheres and IDLH conditions. The air from the cylinders is then delivered through a regulator to bring it down to a breathable pressure (OSHA 2011). SCBAs usually rely on either the demand or pressure demand modes of operation.

SCBAs are commonly used by firefighters and other first responders for IDLH situations or when the types of contaminants and their concentrations are unknown and being tethered to a breathing air source using an airline is impractical. Drawbacks of SCBAs include their weight, limited duration of use, and decreased maneuverability while wearing them. For IDLH conditions, the highest level of respiratory protection is required. Specifically, a full-facepiece pressure demand SCBA certified by NIOSH for a minimum service life of 30 minutes or a combination full-facepiece pressure demand SAR with auxiliary self-contained air supply is required. Respirators provided only for escape from IDLH atmospheres must be NIOSH-certified for escape from the atmosphere in which they will be used (OSHA 1998). Use times for SCBAs are dependent on the size of the tank, amount of pressure in the tank, and physical exertion level of the worker, with typical ranges being between 20 and 45 minutes (OSHA 2011).

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3

Respirator Classification

Craig E. Colton

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3.1 Introduction

Respirator classification is fundamental knowledge for respirator selection. It also establishes the terminology used for specifying the respirator type or class needed for various applications. Classification has primarily been based on the mode of operation of the respirator and the type of respiratory inlet covering.

A respiratory inlet covering is the part of the respirator that covers the mouth and nose (respiratory inlets) of the wearer. There are many designs including facepieces, hoods, or helmets. The way in which the respirator works and its respiratory inlet covering determine its capabilities and limitations and the level of protection provided. Knowing the various respirator classes allows the occupational safety and health professional to select and matches the respirator to the work task properly. While differences in terminology exist around the world, classification on these bases has been the norm for many years. Recently, there has been an effort through the International Organization for Standardization (ISO) to classify respirators according to their performance in laboratory tests. Both these approaches to classification are discussed.

While many countries have their own performance standards and methods for assessing respirator conformity, the current classification systems result in similar respirator product design. The performance ratings can range from being quite similar to being very different. For example, respirator particle filters may differ between countries. Sometimes the filter efficiency requirements might be the same (e.g., 95% efficiency), but measured differently, resulting in different laboratory performance. This can cause challenges when trying to make a global recommendation for a common hazard. A case in point was when Severe Acute Respiratory Syndrome (SARS) struck the world. One of the recommendations to reduce healthcare worker exposure was to wear a National Institute for Occupational Safety and Health (NIOSH)-approved N95 particulate-removing, filtering-facepiece respirator. The recommendation of a specific United States (US) product created a shortfall as the disease spread to other locations around the world. At the same time, other potentially acceptable respirators were available that were similar to the "N95," such as the particle-filtering half-mask with a "P2" filter, meeting requirements in EN 149 (2001) (FFP2). The main difference between the two filters at that time was one underwent filter loading during testing and the other did not. In healthcare settings extreme filter loading is typically not an issue.

Challenges are also created by today's system for multinational companies trying to standardize on the same respiratory protection. While a respirator sold around the world may be identical, different countries often assign a different level of protection to it (i.e., assigned protection factor [APF]).

The United States and countries that align with it in a normative way follow classification as described in Title 42 of the Code of Federal Regulations, part 84 (42 CFR 84). This regulation also establishes legal terminology with the gaps filled in by the American National Standards Institute Z88.2-2015. Thus US respirator classification is determined by NIOSH testing in accordance with 42 CFR 84. Respirator classes can further be aligned with the approval number assigned by NIOSH as a result of this testing.

European countries and those leaning toward Europe's method of respirator classification follow the classification and terminology outlined in EN 133 (2008). This classification is essentially by respirator mode of operation, has similar classes as those found in the United States, but with different

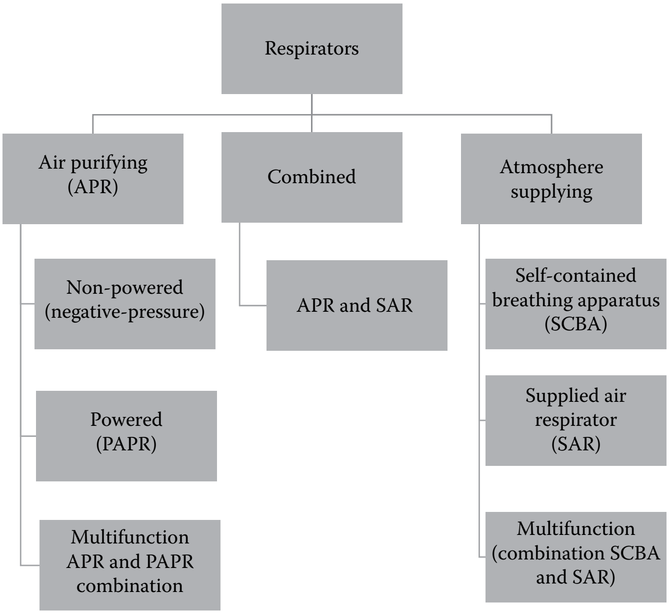
Respirators
Air purifying (APR)
Combined
Atmosphere supplying
Non-powered (negative-pressure)
Powered (PAPR)
Multifunction APR and PAPR combination
APR and SAR
Self-contained breathing apparatus (SCBA)
Supplied air respirator (SAR)
Multifunction (combination SCBA and SAR)

FIGURE 3.1
US respirator classification overview.

test requirements and terminology. Figures 3.1 and 3.2 illustrate these two approaches to respirator classification.

Finally, ISO has released a technical specification outlining a new method for respirator classification for respirators meeting its standards (ISO/TS 16973). ISO, like Europe, uses the term respiratory protective device (RPD) instead of respirator. Each RPD meeting ISO requirements will have an individual classification based on its performance specified in the relevant ISO performance standards (forthcoming). The primary difference between the existing classification systems and the new ISO classification system is that current methods allow us to visually identify the respirator type and thus identify its performance (e.g., half-facepiece respirator with N95 filters having an APF of 10). The new ISO method can result in similar looking devices having different performance levels, while different looking devices may have the same performance.

3.2 US Respirator Classification

Respirator classes in the United States are based on respirator design (e.g., pressure-demand, self-contained breathing apparatus [SCBA]) and are established by NIOSH testing as to the type of protection (e.g., organic vapors and particles). The respiratory inlet covering classification (e.g., half-facepiece or

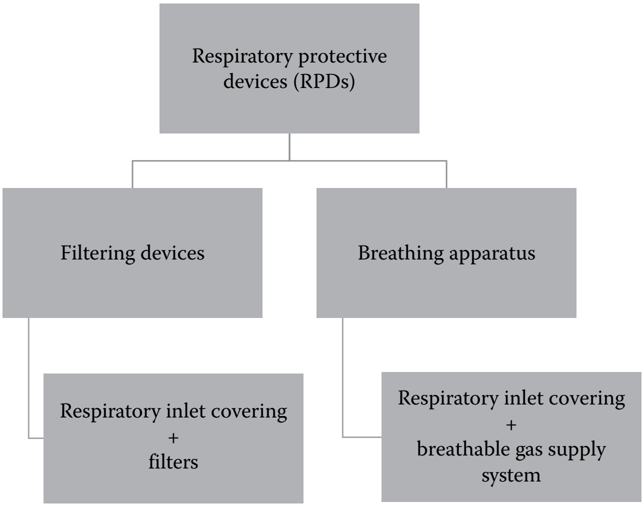
Respiratory protective devices (RPDs)
Filtering devices
Breathing apparatus
Respiratory inlet covering + filters
Respiratory inlet covering + breathable gas supply system

FIGURE 3.2
EN respirator classification overview.

full-facepiece) is an important part of classification for identifying the APF. Figure 3.1 provides a high-level overview of US respirator classification and the major respirator groups. The term air-purifying respirator is perhaps self-explanatory. Using particle filters or gas- and vapor-removing elements, the workplace air is "purified" by these devices before breathing it in. Atmosphere-supplying respirators are the preferred term for respirators that supply a respirable atmosphere, independent of the workplace atmosphere. Sometimes this class is called air-supplied respirators, albeit incorrectly. While some of these devices supply air to the wearer, others provide different types of respirable or breathable gas such as oxygen or oxygen-enriched air. Calling these devices air supplied is a misnomer.

Here we provide an outline of respirator classification in the United States. This outline lists NIOSH terminology, the NIOSH approval number prefix, and the corresponding subpart of 42 CFR 84. This allows the reader to look up specific test requirements in 42 CFR 84 or in the online NIOSH-Certified Equipment List.

1. Air-purifying respirators (APRs) with quarter-, half- (includes filtering-facepiece respirators) and full-facepieces and mouthpiece and nose clip, helmet, or hood
   a. Non-powered APR
      i. Gas and vapor removing (TC-14G or TC-23C) (Subpart I or L)
      ii. Particulate removing (TC-84A) (Subpart K)
      iii. Combination of (i) and (ii) above (TC-84A or TC 14G)

    b. Powered air-purifying respirators (PAPRs) (Subpart KK)
        i. Gas and vapor removing (TC-23C)
        ii. Particulate removing (TC-21C)
        iii. Combination of (i) and (ii) above (TC-23C)
    c. Multifunctional (Combination of an APR and PAPR)
        i. Gas and vapor removing (TC-23C)
        ii. Particulate removing (TC-21C)
        iii. Combination of (i) and (ii) above (TC-23C)
2. Atmosphere-supplying respirators
    a. SCBA with facepiece or mouthpiece and nose clip (TC-13F) (Subpart H)
        i. Closed circuit
            A. Demand
            B. Pressure demand
            C. Escape respirator (TC-13G)
        ii. Open circuit with facepiece, mouthpiece, and nose clip or hood
            A. Demand
            B. Pressure demand
            C. Continuous flow (escape only)
    b. Supplied-air respirator (SAR) (TC-19C) (Subpart J)
        i. Type C or CE SAR (airline respirator)
            A. Continuous flow
            B. Demand
            C. Pressure demand
    c. Multifunctional (Combination of SCBA and SAR) with facepiece, mouthpiece, and nose clip (TC-13F)
3. Combined atmosphere-supplying and air-purifying respirators (TC-14G, TC-21C, TC-23C, or TC-84A)

3.2.1 Air-Purifying Respirators

As seen from the outline, all of the air-purifying respirators potentially can utilize the same set of particle filters and chemical cartridges for removal of workplace contaminants. The choice is limited only by those that the manufacturer chooses to make and get approved by NIOSH. Oftentimes "negative pressure" is used to describe air-purifying respirators where the filtration is dependent upon the wearer inhaling (non-powered), creating negative pressure inside the respirator facepiece drawing air through the air-purifying element. In the United States, air-purifying elements are divided into (1) filters—devices designed to remove particles and (2) cartridges—devices designed to remove gases and vapors. It would be clearer to say particle filters and chemical cartridges to make this distinction, but shorthand seems to have taken over by referring to these simply as filters or cartridges, respectively.

For air-purifying respirators, particle filters are classified in one of three series, N-, R-, or P-series. Each series has three levels of filter efficiency of either 95%, 99%, or 99.97% as determined in a laboratory test. They are referred to as 95, 99, or 100 level filters, respectively. This filter terminology only applies to particle filters for non-PAPRs. PAPRs use a particle filter called high efficiency. It is the only particle filter available for NIOSH-approved PAPR. This filter is sometimes called high-efficiency particulate airfilter (HEPA) which is a trade term. Table 3.1 summarizes filter information and its use. It is important to note that respirators are often referred to by their filter name. The class of respirator is determined by the filter. It is

TABLE 3.1

Description of Filter Classes Certified under 42 CFR 84

Class of Filter	Efficiency	Contaminant Type	Service Time
N-Series		Solid and water-based particulates (i.e., non-oil aerosols)	Nonspecific[a]
N100	99.97%		
N99	99%		
N95	95%		
R-Series		Any	One work shift[a,b]
R100	99.97%		
R99	99%		
R95	95%		
P-Series		Any	Non-specific[a,c]
P100	99.97%		
P99	99%		
P95	95%		
High efficiency	99.97%	Any	Non-specific[a,c,d]

Source: Adapted from *NIOSH, NIOSH Guide to the Selection and Use of Particulate Respirators Certified Under 42 CFR 84. DHHS (NIOSH) Publication No. 96-101.* NIOSH, Cincinnati, OH, 1996, https://www.cdc.gov/niosh/docs/96-101/default.html (accessed 8 May 2017).

[a] Limited by considerations of hygiene, damage, and breathing resistance.

[b] No specific service time limit when oil aerosols are not present. In the presence of oil aerosols, service time may be extended beyond 8 hours of use (continuous or intermittent) by (a) demonstrating that extended use will not degrade the filter efficiency below the certified efficiency level, or (b) demonstrating that the total mass loading of the filter is less than 200 mg (100 mg per filter for dual-filter respirators).

[c] The P100 filter must be color-coded magenta. The Part 84 Subpart KK HEPA filter on PAPRs will also be magenta, but the label will be different from the P100 filter, and the two filters cannot be interchanged. Requirements on service time for P-series filters are discussed in a NIOSH letter to Respirator Users (1997).

[d] The high-efficiency filter is only used on PAPRs.

important to recognize that this class does not define a specific design of the respirator. For example, it is common in some industries (e.g., healthcare) to refer to an N-95 respirator. They are typically referring to a filtering-facepiece respirator with an N95 filter approval, however the term N95 respirator also includes elastomeric half-facepieces and full-facepieces with an N95 filter attached to them. In this respirator class, there are three types or designs of N95 respirators.

Two classes of gas- and vapor-removing respirators exist in the United States. One is the chemical-cartridge respirator. The second is the gas mask. A gas mask is a respirator that uses canisters for capturing gases and vapors. The greatest difference between these two classes is the increased service time of the gas mask. Gas masks are not as popular as they once were, and the choices of canisters and their use have been declining. The most popular gas mask is one designed for chemical, biological, radiological, and nuclear (CBRN) use. The CBRN respirator class became available on the industrial market after the attacks on the United States on September 11, 2001. Chemical-cartridge respirators with either a half- or full-facepiece are the most popular gas- and vapor-removing respirator. Current “protections” (type of chemical cartridges) approved by NIOSH are identified in Table 3.2. In addition to these basic types, the manufacturer can get cartridges approved with a combination of protections.

3.2.2 Atmosphere-Supplying Respirators

SCBA is one of the types of atmosphere-supplying respirator. These have been available for years, but in the closed-circuit SCBA class another category has been added recently. As a result of mining accidents, NIOSH has developed criteria for a closed-circuit SCBA for use in mines. This respirator class is referred to as a closed-circuit escape respirator (CCER). These criteria

TABLE 3.2

Description of Chemical Cartridges Certified under 42 CFR 84

Chemical Cartridge Class	Typical Contaminants[a]	Color Code Used on Cartridge
Acidic gases	Cl, ClO_2, H_2S, HCL, SO_2, and HF	White
Basic gases	NH_3 and CH_3NH_2	Green
Organic vapors	Wide variety of organic vapors	Black
Formaldehyde	CH_2O	Olive green
Mercury vapors	Hg	Olive green/orange
Multi-gas	Wide variety of contaminants	Olive green
Vinyl chloride	VC	Olive green
Other gases and vapors not listed above	NO_x	Olive green

[a] Not all chemical cartridges are suitable for all contaminants within the class. See the label on the chemical cartridge for specific contaminant designations for which the cartridge is suitable.

replace those previously used for self-contained self-rescuers (SCSRs). The specific criteria can be found in subpart O of 42 CFR 84. As a result they have a unique approval number separate from other SCBA, TC-13G.

SARs are a subset of atmosphere-supplying respirators that supply air to the wearer. NIOSH allows for three types of SAR to be approved, Type A, Type B, and Type C. Today the only type of SAR on the US market is the Type C SAR. This device is often referred to as an airline respirator because it typically has a compressed-air hose that connects to either large tanks or a compressor to supply breathable air to the wearer. A variant of the Type C is the Type CE. The "E" designates it is classified as an abrasive-blasting respirator. This respirator class is equipped with additional devices designed to protect the wearer's head and neck against impact and abrasion from rebounding abrasive material.

3.2.3 Combined Respirators

Combined respirators are respirators where the functions of two respirator classes have been combined into one device. Presently there is only one combined respirator in the United States where the functions of an air-purifying respirator have been combined with the functions of a SAR. The respirator is designed to be used predominantly in the airline respirator mode but, depending on the specific model, can be equipped with an assortment of filers and cartridges, although the approval label should be consulted. This combined respirator allows one to select the air-purifying element that is appropriate for the workplace. The respirators are primarily used in the airline mode. The airline mode provides a higher APF than the air-purifying mode. The air-purifying function allows the respirator to be used when the air supply is lost or the worker needs to disconnect from the air supply in order to move around. The advantage is the wearer does not have to remove the respirator facepiece when disconnected from the air supply. This allows the wearer to have some respiratory protection while disconnecting in one place and reconnecting in another or exiting the area without the need for the airline. The types of respirators making up the combined respirator must meet the minimum requirements for each respirator type. The combined respirator will be classified by the type of respirator in the combination that supplies the least protection to the user. In this example it is classified as an air-purifying respirator.

3.2.4 Performance

Performance factors such as fit, filter and cartridge efficiency, breathing resistance, and valve leakage are assessed in individual tests by NIOSH. The overall performance of the respirator is described by the APF. The APF is the workplace level of respiratory protection that a respirator or class of respirators is expected to provide to employees when the employer implements a continuing effective respiratory protection program as outlined in 29 CFR 1910.134, the Occupational Safety and Health Administration

(OSHA) respiratory protection standard. It takes into account all leakage sources such as fit, filter, and valve leakage. These numbers were established by OSHA and assigned to the various NIOSH classes of respirators as a result of rulemaking (*Federal Register* 2006). OSHA assigned these numbers after thoroughly reviewing the available literature, including the various analyses by respirator authorities, as well as quantitative analyses of data from workplace protection factor (WPF) and simulated workplace protection factor (SWPF) studies, comments submitted to the record, and hearing testimony. OSHA relied primarily on WPF and SWPF studies, since they focus on the performance characteristics of the respirator only (i.e., not improper use). This procedure, according to OSHA, ensured that only carefully designed and executed WPF and SWPF studies were included in the analysis. The performance levels (APFs) established as a result of this effort are listed in Table 3.3.

TABLE 3.3

APFs from OSHA

	Respiratory Inlet Covering[a]				
Type of Respirator	**Quarter Mask**	**Half Mask**	**Full Facepiece**	**Helmet/ Hood**	**Loose-Fitting Facepiece**
Air-purifying respirator	5	10[b]	50	----	----
PAPR	-----	50	1000	25/1000[c]	25
SAR or airline respirator Demand mode	____	10	50	____	____
Continuous flow mode	____	50	1000	25/1000[c]	25
Pressure-demand or other positive-pressure[d] mode	____	50	1000	____	____
SCBA Demand-mode	____	10	50	50	____
Pressure-demand or other positive-pressure[d] mode	____	____	10,000	10,000	____

Source: Adapted from Code of Federal Regulations, *Title 29 Part 1910.134, Respiratory Protection*. US Government Printing Office: Washington, DC, 2009.

[a] Respiratory inlet covering—That portion of a respirator that forms the protective barrier between the user's respiratory tract and an air-purifying or atmosphere-supplying respirator. They may be tight- or loose-fitting in design. It may be a facepiece, helmet, hood, or mouthpiece/nose clamp.

[b] This APF category includes FFRs and half masks with elastomeric facepieces.

[c] The employer must have evidence provided by the manufacturer that testing of these respirators demonstrates performance at a level of protection of 1000 or greater to receive an APF of 1000. This level of performance can best be demonstrated by performing a WPF or SWPF study or equivalent testing. Absent such testing, all other PAPRs and SARs with helmets/hoods are to be treated as loose-fitting facepiece respirators and receive an APF of 25.

[d] Other positive-pressure mode-term used by NIOSH to identify atmosphere-supplying respirators operating in the continuous flow mode, instead of using a pressure-demand valve, that meets the pressure-demand approval criteria. These are listed as an approved pressure-demand respirator on the NIOSH approval label (Metzler 1996).

3.3 EN RPD Classification

In Europe, the European Standard EN 133 establishes RPD classifications. The preferred term in Europe is RPD instead of the term respirator. This classification identifies two main categories of RPDs (Figure 3.2). Instead of the term air-purifying respirators, the term filtering devices is used. In place of atmosphere-supplying respirators, the term breathing apparatus (BA) is used. This points out another common distinction as the term RPD is often reserved for filtering devices. In this classification the two major categories are sometimes called out as RPD and BA. The classification scheme comes from the basic design. The European approach has been to develop a standard for each product category compared to the approach in the United States where the requirements are grouped in subparts of 42 CFR 84. The European scheme has eight different standards to cover all of the SCBA. There are also separate standards for the facepieces. Another difference in terminology is Europe refers to everything used on an air-purifying respirator as a filter whether it is designed to remove particles or gases and vapors. Table 3.4 lists the particle filter RPD classes and Table 3.5 lists the gas filters under EN standards. The EN standards use a mask in place of a facepiece and a half-mask instead of a half-facepiece.

The outline below identifies all of the possible classifications from EN standards. The EN standard number for the RPD is identified in parenthesis in this outline. The most current version can be found easily online.

1. Filtering devices
    a. Unassisted
        i. Filters—used with full, half, quarter, or mouth piece assemblies
            A. Gas filters and combined filters (gas + particle filter) (EN 141)
            B. Particle filter (EN 143)
            C. AX gas filters and combined filters against low-boiling (BP < 65°C) compounds (EN 371)
            D. SX gas filters and combined filters against specific-named compounds (EN 372)
            E. Filters with breathing hoses—(Non-facepiece mounted filters) Particle, gas, and combined filters (EN 10283)
        ii. Filtering facepieces (FFR)
            A. FFR to protect against particles (EN 149)
            B. Valved FFR to protect against gases or gases and particles (EN 405)

TABLE 3.4

Maximum Filter Penetration for EN Particle Filters

Filter Class[a]	Filter Efficiency: Sodium Chloride (%)	Filter Efficiency: Paraffin Oil Test (%)	Contaminant Type
P1	80	80	Any
P2	94	94	Any
P3	99.05	99.05	Any

Source: EN 143:2000. *Respiratory Protective Devices—Particle Filters—Requirements, Testing and Marking*. CEN, European Committee for Standardization, Management Centre: rue de Stassart, 36, B-1050 Brussels, Belgium, 2000, p 1–34.

[a] Filter may be classified as single shift use only or as re-usable meaning it can be used for more than a single shift.

TABLE 3.5

Description of EN Chemical Cartridges

Chemical Cartridge Class Type/Class	Typical Contaminants[a]	Color Code Used on Cartridge
A/1, 2, or 3	Certain organic vapors with a boiling point > 65°C as specified by the manufacturer	Brown
B/1, 2, or 3	Certain inorganic gases and vapors as specified by the manufacturer	Grey
E/1, 2, or 3	Sulfur dioxide and other acidic gases and vapors as specified by the manufacturer	Yellow
K/1, 2, or 3	Ammonia and organic ammonia derivatives as specified by the manufacturer	Green
AX	Certain organic gases and vapors with a boiling point ≤65°C as specified by the manufacturer	Brown
SX	Specific-named gases and vapors as specified by the manufacturer	Violet
Multiple-type gas filters	Filters for a combination of two or more of the above types excluding SX	Shall have all applicable colors for the combination
Combined filters	One of the above filter types incorporating a particle filter	Applicable color for the gas/vapor and white for the particle filter
NOP3	Nitrogen oxides, e.g., NO, NO_2, and NO_x	Blue-white
HgP3	Mercury	Red-white

Source: Adapted from EN 14387:2004+A1. *Respiratory Protective Devices—Gas Filter(s) and Combined Filter(s)—Requirements, Testing, Marking*. CEN, European Committee for Standardization, Management Centre: rue de Stassart, 36, B-1050 Brussels, Belgium, 2004, p 1–25.

Gas filters may be classified as single shift use only or as reusable meaning it can be used for more than a single shift.

            C. Half-facepieces without inhalation valves and with separable filter to protect against gases or gases and particles (EN 1827)
        iii. Self-rescuer
            A. Filtering devices with hood for self-rescue from fire (EN 403)
            B. Filter self-rescuers (EN 404)
    b. Assisted
        i. Powered filtering devices incorporating helmet or hood (EN 12941)
        ii. Powered assisted filtering devices incorporating full, half, or quarter facepieces (EN 12942)
2. Breathing apparatus
    a. Not self-contained
        i. Fresh air hose breathing apparatus (may not be on market anymore as similar devices are no longer marketed in the United States)
            A. Fresh air hose breathing apparatus for use with full face, half face, or mouth piece assemblies (EN 138)
                i. Unassisted
                ii. Manually assisted
            B. Powered fresh air hose breathing apparatus incorporating a hood (EN 269)
        iii. Compressed airline breathing apparatus
            A. Compressed airline breathing apparatus for use with full, half, or mouth piece assemblies (EN 139)
            B. Compressed airline breathing apparatus incorporating a hood (EN 270)
            C. Compressed airline or powered fresh air hose breathing apparatus incorporating a hood for abrasive-blasting operations (EN 271)
            D. Light duty compressed airline breathing apparatus incorporating a helmet or hood (EN 1835)
            E. Light duty construction compressed airline breathing apparatus incorporating a full, half, or quarter facepiece (EN 12419)
    b. Self-contained
        i. Open circuit
            A. Self-contained compressed air breathing apparatus (EN 137)
            B. Self-contained compressed air diving apparatus (EN 250)

    - ii. Closed circuit
        - A. SCBA compressed oxygen or compressed oxygen-nitrogen type (EN 145)
- c. Escape apparatus
    - i. Open circuit
        - A. Self-contained compressed breathing apparatus with full, or mouth piece assemblies (EN 402)
        - B. Self-contained compressed air breathing apparatus incorporating a hood (compressed air escape apparatus with hood) (EN 1146)
    - ii. Closed circuit
        - A. Self-contained BA—Compressed oxygen escape apparatus (EN 400)
        - B. Self-contained BA—Chemical oxygen (KO_2) escape apparatus (EN 401)
        - C. Self-contained BA—Chemical oxygen ($NaClO_3$) escape apparatus (EN 1061)

Facepieces are specified one of three EN standards: full-facepiece, EN 136 (1998); half- and quarter- facepiece, EN 140 (1999); and mouthpiece, EN 142 (2002). The helmet and hood requirements are specified in the relevant product standard. EN standards use the term "unassisted" and "assisted" to identify RPDs, whereas the United States refers to "negative pressure" and "powered" air-purifying respirators, respectively.

3.3.1 Particle Filters

Particle filters used with filtering devices are divided into classes based on efficiency, low, medium, and high efficiency, P1, P2, P3, respectively. They are tested against both oil and non-oil test agents, thus no distinction is made between N and R or N and P as in the United States. The efficiencies are determined by a laboratory test similar to those used in the United States. The EN particle filter classes and their use are summarized in Table 3.4.

3.3.2 Gas and Vapor Filters

A variety of gas filters are described in EN standards and are identified in Table 3.5. Many of the gas filters are similar to ones in the United States. However, a gas filter classification lacking in the United States is the AX filter. The AX filter, used for organic gases as opposed to organic vapors, is designed for the more volatile organic compounds. These compounds have been identified as organic chemicals with a boiling point less than 65°C. The purpose of the AX classification is to identify those organic chemicals that would be most volatile. If an organic vapor filter were used, it may not have sufficient capacity for the compound to provide a reasonable service life. Often times the AX filter is merely a larger organic vapor (Type A) filter (i.e., more carbon). The AX filter is a one-shift only filter which reduces the chance of migration occurring with reuse. In the United States, organic vapor cartridges are used for this application. A cartridge change schedule is required to be established using objective data along with a use restriction of no longer than one shift for organic chemicals with a boiling point less than 65°C.

3.3.3 Performance

Overall performance of RPDs meeting EN standards is assessed in the laboratory. A device designed to meet the requirements of a given European Standard should perform, when tested in an approved testing laboratory, at or below the maximum total inward leakage (TIL) specified in the standard. This is a very specific test spelled out in the EN standards. It measures the total amount of test agent leaking into the respirator from all potential routes including face-seal leakage, valve leakage, and filter penetration as indicated by Equation 3.1. Because of the test particle size used, significant filter penetration in the laboratory test can occur for P1 and P2 filters which would not occur in the workplace when properly selected. The resultant measurement is the percent penetration of the test agent.

$$\%\text{TIL} = \frac{C_2}{C_1} \times 100 \tag{3.1}$$

where C_1 is the challenge concentration

C_2 is the measured concentration inside the RPD

If the RPD meets the maximum TIL value requirement (i.e., the TIL value is less than the maximum allowed), then the nominal protection factor (NPF) can be determined. This inward leakage value can be converted to a "nominal protection factor" using Equation 3.2.

$$\text{NPF} = \frac{100}{\text{maximum percentage of TIL permitted}} \tag{3.2}$$

As the term implies, it is a protection level that is "supposed" to be achieved by any RPD wearer. There are many issues with using the TIL test as an indicator of workplace performance. The laboratory tests:

- Do not represent workplace activities.
- Only involve a small number of individuals and may not be representative of the population of RPD wearers.
- Use an aerosol that may not be representative of the workplace.
- Sampling times are shorter than time worn in the workplace.
- Environmental conditions are different from the workplace.

Depending on the RPD tested, the NPF may be much lower or higher than a WPF. The two are not correlated. At one time the NPF was used solely as the "protection factor" for RPD selection in Europe. Because of the separation of the NPF from the workplace, the EN community has been establishing APF for the RPD classes. Sometimes the NPF is used as the APF and in other cases WPF studies may have been reviewed. These WPF studies seem to be mostly WPF studies performed in Europe on European RPD. It would appear the similarities in filtering devices would allow the use of WPF studies from the United States. However, fit testing, which has been shown to have a significant impact on the protection received by wearers of air-purifying half facepiece respirators, is not widely practiced in Europe (Colton 1999). In addition some of the European APFs have been set by the insurance industry using professional judgment. As a result sometimes there is an APF, and sometimes the NPF is used. Secondly, there can be substantial differences in the APF used between European countries. Table 3.6 lists NPFs and examples of APF used in different countries for different types of RPDs. Notice that when looking at the same respirator performance data, countries have reached different decisions on the APF.

3.4 ISO RPD Classification

In 2001, the Technical Committee on Personal Safety—Protective Clothing and Equipment (TC94) of the ISO voted to form a subcommittee (SC15) to develop performance standards for RPDs. ISO is a worldwide federation of national standards bodies (ISO member bodies). The subcommittee's goal is to standardize the performance requirements for RPDs used by wearers in hazardous environments. Reasons for the new standards include harmonization of RPD performance requirements and a chance to make standards more "wearer centric" than existing standards. An underlying approach for ISO is to base the RPD requirements on human factors so the RPD design takes into account the impact on the wearer. A benefit could be the elimination of different APF for the same RPD based on the country where it is used. The effect on worldwide harmonization depends on the voluntary adoption of these standards by member bodies across the world.

The major result of this effort will be the development of two standards identifying performance requirements for all RPDs. One standard is for supplied breathable gas RPDs and the other is for filtering RPDs. Many ISO standards and technical specifications addressing the testing and use of these RPDs have been developed to support these two new performance standards. In early 2016, ISO published a Technical Specification on the classification of RPDs meeting these two ISO standards (ISO/TS 16973 2016). The respirator classes depart from the previous two classification schemes discussed in that

TABLE 3.6

NPFs and APFs Used in Different Countries

			APFs Used in Some Countries				
Description	**Class**	**NPF[a]**	**Fin[b]**	**D[c]**	**I[d]**	**S[e]**	**UK[f]**
Filtering half mask	FFP1	4	4	4	4	4	4
	FFP2	12	10	10	10	10	10
	FFP3	50	20	30	30	20	20
Valved filtering half mask	FFGasX P1	4		4	–		4
	FFGasX	50		30	–		10
	FFGasX P2	12		10	–		10
	FFGasX P3	33		30	–		10
Half mask and quarter mask with filter	P1	4	4	4	4	4	4
	P2	12	10	10	10	10	10
	P3	48		30	30		20
	GasX	50	20	30	30	20	10
	GasX P1	4					
	GasX P2	12					
	GasX P3	48		30	–		
Filtering half mask without inhalation valves	FM P1	4		4	–		4
	FM P2	12		10	–		10
	FM P3	48		30	–		20
	FM GasX	50		30	–		10
	FM GasX P1	4					
	FMGasX P2	12					
	FMGasX P3	48					

(*Continued*)

TABLE 3.6 ***(Continued)***

NPFs and APFs Used in Different Countries

Description	Class	NPF[a]	APFs Used in Some Countries				
			Fin[b]	D[c]	I[d]	S[e]	UK[f]
Full-face mask (all classes)	P1	5	4	4	4	4	4
	P2	16	15	15	15	15	10
	P3	1000	500	400	400	500	40
	GasX	2000	500	400	400	500	20
	GasX P1	5					
	GasX P2	16					
	GasX P3	1000		400			20
Powered filtering device incorporating a hood or a helmet	TH1	10	5	5	5	5	10
	TH2	50	20	20	20	20	20
	TH3	500	200	100	200	200	40
Powered filtering device incorporating full-face mask, half mask, or quarter mask	TM1	20	10	10	10	10	10
	TM2	200	100	100	100	100	20
	TM3	2000	1000	500	400	1000	40
Compressed airline breathing apparatus with demand valve—Part 1: Apparatus with a full-face mask		2000	1000	1000	400	1000	400
Compressed airline breathing apparatus with demand valve—Part 2: Apparatus with a half mask at positive pressure		200					
Continuous flow compressed airline breathing apparatus	1A/1B	10					
	2A/2B	50					
	3A/3B	200					
	4A/4B	2000					

(*Continued*)

TABLE 3.6 ***(Continued)***

NPFs and APFs Used in Different Countries

Description	Class	NPF[a]	APFs Used in Some Countries				
			Fin[b]	D[c]	I[d]	S[e]	UK[f]
Fresh air hose breathing apparatus	Half mask	50		100	–		10
	Full-face mask	2000	500	1000	400	500	40
Powered fresh air hose breathing apparatus incorporating a hood		200		100			
Self-contained open circuit compressed air breathing apparatus	Negative pressure demand	2000		>1000	400		40
	Positive pressure demand						
		2000		>1000	1000		2000
Self-contained closed-circuit compressed oxygen/nitrogen breathing apparatus		2000	500	>1000	400		500
Self-contained open circuit compressed air breathing apparatus with full face mask or mouth piece assembly for escape		2000		>1000	–		

Source: Adapted from EN 529:2005. *Respiratory Protective Devices—Recommendations for Selection, Use, Care and Maintenance—Guidance Document*. CEN, European Committee for Standardization, Management Centre: rue de Stassart, 36, B-1050 Brussels, Belgium, 2005, p 1–50.

[a] NPF = Nominal protection factor

[b] Fin = Finland

[c] D = Germany

[d] I = Italy

[e] S = Sweden

[f] UK = United Kingdom

classification is based on respirator performance rather than design. Instead of respirator performance being identified by respirator design and mode of operation, for example, half-facepiece respirator with N95 filters, ISO will now base classification on the testing outcome.

As a result of the two standards, ISO has classified RPDs into two main categories: supplied breathable gas RPDs and filtering RPDs. While the RPD will look similar to today's RPD, performance level may differ. Each RPD will have an individual classification based on its performance specified in the relevant performance standards. This classification scheme does not lend itself to be summarized by an outline approach because of the huge number of classes that potentially exist. On the other hand this classification does not restrict potential RPDs that could be available because the standards would not allow it.

3.4.1 RPD Classification Overview

In the ISO classification scheme, the basic classification, which applies to all RPDs, will be marked in the following order:

a. Protection class
b. Work rate class
c. Respiratory-interface class

The basic classification is common to all RPDs. After that, the RPD classification identifies it as either supplied breathable gas or filtering RPD. For supplied breathable gas RPDs, the classification will then include a designation as Sxxx or SY. The designation "xxxx" is a place holder for the volume of breathable gas contained in the portable cylinder. The SY designation of the RPD uses an external source of breathable gas through an airline. Supplied breathable gas RPD that have an external supply of breathable gas (e.g., compressor or air cylinders cascaded together) will be classified as "SY." These devices are the ISO version of airline respirators.

For filtering RPDs, the classification for the particle filter and/or the gas filter will be next.

ISO also establishes classes of respirators for many special applications. In this case the classification will indicate which requirements the respirator meets and becomes part of the classification nomenclature. If the RPD meets requirements of any of the special applications these will be listed next.

The special applications identified by ISO are

- Firefighting
- Chemical, biological, radiological, and nuclear
- Marine
- Mining

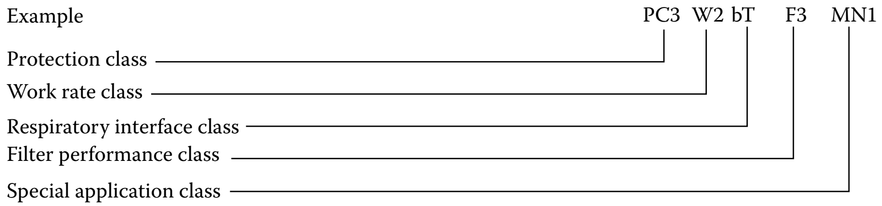
Example
PC3 W2 bT F3 MN1
Protection class
Work rate class
Respiratory interface class
Filter performance class
Special application class

FIGURE 3.3
ISO RPD classification order (see text for explanation).

- Abrasive blasting
- Welding
- Escape

Figures 3.3 shows what a classification code looks like and how to read it.

3.4.2 Basic Classification

3.4.2.1 Protection Class

Six classes of protection are established indicating a relative ranking of how protective the RPD can be when used properly. The classes are listed in Table 3.7. Performance is discussed later.

3.4.2.2 Work Rate

The second part of the classification is work rate. Respirators will be classified based on one of four work rate classes, W1 to W4, where W1 is light-moderate work and W4 is maximal work effort rates. The work rate class is derived from the results of a "work-of-breathing" laboratory test. The idea behind

TABLE 3.7
ISO Protection Classes

Protection Class	TIL$_{Max}$ (%)[a]
PC1	20
PC2	5
PC3	1
PC4	0.1
PC5	0.001
PC6	0.0001

[a] TIL = total inward leakage, the ratio of the concentration of test agent inside the respirator compared to the concentration outside the RPD during the test and expressed as a percentage.

this is the worker should use a less burdensome RPD for heavier work. This part of classification identifies RPDs based on this factor and makes these RPDs identifiable to the user.

3.4.2.3 Respiratory Interface

The third indicator of classification identifies the type of respiratory inlet covering used. In ISO terms this is called the respiratory interface. The respiratory-interface class first describes the coverage area of the wearer followed by an indication of whether it is tight-fitting (T) or loose-fitting (L) RPD. This indication identifies if fit testing is necessary and whether there needs to be concerned about preventing conditions that would interfere with the fit of the RPD. Table 3.8 lists the respiratory-interface classes and matches them to respiratory inlet coverings used in the United States and European classification schemes. The table includes some classes of respiratory interface that can only be considered theoretical at this point in time, but leaves the door open for innovation (e.g., aL or aT). Class bT might look like a FFR or elastomeric half facepiece. Table 3.8 describes the coverage areas for the respiratory-interface classification.

3.4.3 Advanced Classification

3.4.3.1 Supplied Breathable Gas RPD Classifications

Supplied breathable gas RPDs that have a fixed volume of breathable gas (i.e., self-contained) are classified by the volume of breathable gas available and are designated by the letter “S” followed by the gas capacity of the cylinder

TABLE 3.8

ISO Respiratory Interface (RI) Classes

RI Class	RI Area of Coverage	Type	Existing Respiratory Inlet Coverings
eL	e—More than head, up to complete body	L-loose fitting	Supplied-air suits
eT	e—More than head, up to complete body	T-tight fitting	–
dL	d—head	L-loose fitting	Hoods and helmets
dT	d—head	T-tight fitting	Hoods with neck dams
cL	c—Face	L-loose fitting	–
cT	c—Face	T-tight fitting	Full-facepiece
bL	b—Nose and mouth	L-loose fitting	–
bT	b—Nose and mouth	T-tight fitting	Quarter or half facepiece
aL	a—Mouth only	L-loose fitting	–
aT	a—Mouth only	T-tight fitting	Mouthpiece

in liters rounded down to increments of 150 L up to 900 L and increments of 300 L above 900 L. The classification would look like Sxxxx where x is the volume in liters. Currently in the United States we refer to the size of the device by time (e.g., 30-minute SCBA). Classification based on time can be misleading because it does not take into account the breathing rate of the wearer. The time rating is based on service time on a breathing machine with fixed parameters, which may not match up with the demands of the work environment or the condition of the wearer.

3.4.3.2 Filtering RPD Classification

For filtering devices, the classification identifies the filter class after the respiratory interface. Particle filters are classified by their efficiency and work rate category. ISO established five particle filter efficiency levels based on a "worst case" laboratory test tested at the relevant flowrate paired to the work rate class. The particle filter efficiencies and the corresponding filter class designation are listed in Table 3.9. All particle filters are tested against oil and non-oil test agents, allowing each filter to be used against all particle contaminants. The work rate designation is indicated with a lower case "w" and the work rate number 1–4 after the efficiency (e.g., F1w3).

Gas filters are classified by the kind of gas (type) (e.g., organic vapors and acidic gases) they are designed for and the gas capacity (class 1–4) followed by the work rate rating. A gas filter can be designed for one type of gas only or for multiple gas types. Table 3.10 lists the gas filter types and classes and examples of typical contaminants. Gas filters may also be designed for specific gases listed in Table 3.11. Filter classification and gas capacity are both identified in the classification (e.g., OV2 and ND1).

3.4.3.3 Special Application

Finally, there are codes to indicate whether the respirator meets special application requirements and thus can be classified for one of the aforementioned special applications. These special applications may include specific performance requirements establishing a minimum protection class (PC)

TABLE 3.9

Particle Filter Class

Particle Filter Class	Particle Filter Efficiency (%)	Contaminant Type
F1	≥80.00	Any
F2	≥95.00	Any
F3	≥99.00	Any
F4	≥99.90	Any
F5	≥99.99	Any

TABLE 3.10

Gas Filter Types and Classes

Type	Class	Kind of Gas/Vapor	Typical Contaminants
OV	1,2,3, or 4	Organic vapor	C_7H_8 (toluene) C_6H_{12} (cyclohexane)
OG	1	Organic gas (low boiling, boiling point <65°C	C_3H_6O (acetone) C_4H_{10} (isobutene) C_2H_6O (dimethylether)
AC	1,2,3, or 4	Acidic compounds	Cl_2 (chlorine) H_2S (hydrogen sulfide) HCl (hydrogen chloride) SO_2 (sulfur dioxide)
BC	1,2,3, or 4	Basic compounds	NH_3 (ammonia) CH_3NH_2 (methylamine)
NOX	1,2, or 3	Nitrogen oxides	NO_x (nitrogen oxides)

and work rate class (W). This becomes obvious when thinking about the firefighting application where, due to unknown situations in firefighting, it does not make sense to have a firefighting device in a low PC.

Under the ISO scheme, an RPD is tested as the complete device so the classification of an RPD consists of all of the designations combined. In Figure 3.3, this RPD meets the requirements for PC 3 and work rate class 2. The respiratory interface covers the mouth and nose and is tight fitting. It has a particle filter from class 3 (>99% efficient) and it meets the requirement for the special application of mining class 1.

TABLE 3.11

Specific Gas Filter Types and Classes

Type	Classes	Gas or Vapor
ND	1, 2, or 3	Nitrogen dioxide (NO_2)
HG	1, 2, or 3	Mercury (Hg)
OZ	1	Ozone (O_3)
HCN	1, 2, 3, or 4	Hydrogen cyanide (HCN)
AH	1	Arsine (AsH_3)
HF	1, 2, or 3	Hydrogen fluoride (HF)
CD	1	Chlorine dioxide (ClO_2)
ETO	1 or 2	Ethylene oxide[$(CH_2)_2O$]
FM	1, 2, or 3	Formaldehyde (CH_2O)
MB	1, 2, or 3	Methyl bromide (CH_3Br)
CO	Three classes based on time (20 min, 60 min, or 180 min)	Carbon monoxide (CO)
PH	1 or 2	Phosphine (PH_3)

3.4.4 Classification Examples

The more examples one looks at the more comfortable one gets. This can be illustrated by looking at a few examples of respirators meeting various test requirements and the subsequent classifications. The following classification examples illustrate how the classification system works to identify the RPD.

Example 1. Assume we have a particulate-removing filtering-facepiece respirator which meets ISO requirements of TIL of less than 5%, validated for ISO work rate 1, and having a minimum filter efficiency of 99%. The ISO classification and marking of this RPD would be PC2 W1 bT F3.

Example 2. Assume we have a powered air-purifying respirator with a loose-fitting hood and organic vapor cartridges meeting class 1 capacity tests and validated for ISO work rate 3. The results of the TIL test was a value of less than 1%. The ISO classification and marking would be PC3 W2 dL OV1.

Example 3. Assume we have a pressure-demand SCBA with a full-facepiece that has a TIL of less than 0.001% and validated for work rate 4. The available breathable gas capacity is 1260 L. The ISO classification for this supplied breathable gas RPD would be PC6 W4 cT S1200.

Example 4. Assume we have a half-facepiece respirator with a multigas filter and particle filter. When tested against the ISO requirements, the filter meets the class 1 requirements for organic vapors, acidic gases, basic gases, formaldehyde, chlorine dioxide, hydrogen fluoride, and particle filter requirements of greater than 99.99% efficiency and validated for ISO work rate 1 with a TIL of less than 1%. The ISO classification and marking would be PC3 W1 bT F5 OV1 AC1 BC1 HF1 CD1 FM1.

Tables 3.12 and 3.13 show the versatility of this system and the challenge for change as new classification needs to be taught to respirator users. Table 3.12 lists three similar looking RPDs that have very different classifications. All are half-facepiece respirators with particle filters in the United States and European classification schemes. Table 3.13 lists the

TABLE 3.12

Potential Different Classifications of Three Similar Looking RPDs

Basic Performance Characteristic	Half-Mask Particulate	Half-Mask Particulate	Half-Mask Particulate
Protection class	PC2	PC3	PC1
Respiratory inlet	bT	bT	bT
Work rate	W1	W1	W1
Particle filter efficiency	F2	F3	F3

TABLE 3.13

Three Different Looking RPDs with Identical ISO Classification

Basic Performance Characteristic	Full-Face Assisted	Full-Face Unassisted	Half-Mask Assisted
Protection class	PC4	PC4	PC4
Respiratory inlet	cT	cT	bT
Work rate	W1	W1	W1
Particle filter efficiency	F2	F3	F4

classifications for three RPDs with identical classifications. However, they can look very different from each other. The first listed RPD is a full-face assisted (powered) RPD with an F2 particle filter. The second RPD is a full-facepiece negative pressure RPD using an F3 particle filter. The third RPD is a half facepiece with an F4 particle filter. All are in the same PC and for the same work rates. Their uses could be identical for exposure level except the third RPD that does not provide face/eye protection. The second RPD may be lighter in weight because it does not have a motor/blower system.

3.4.5 Performance

The first part of the classification is the PC and indicates the level of protection the RPD is expected to provide when used within the context of the respiratory protection program specified in ISO/TS 16975-1 (2016). ISO has six PCs established. The PC assigned to the respirator is based on the results of a laboratory TIL test in accordance with the relevant ISO standard. This TIL test is different from the one currently used in Europe. Table 3.7 lists these classes. PC1 is the least protective device and PC6 is the highest level of protection. Actual protection levels have not been assigned to these classes. Protection level is the equivalent of the ISO APF, but is derived from the TIL test. More work needs to be done in order to establish the relationship between the TIL test and the protection levels expected in the workplace. The research to determine the amount of workplace protection that corresponds to the TIL values in Table 3.7 is currently ongoing.

3.5 Summary

The United States and European respirator classification schemes have similar approaches. Both systems classify the respirators by mode of operation and design which indicates the expected performance. The performance is indicated by an assigned number that identifies overall performance—a "protection factor." Performance requirements differ between the two classification schemes resulting in similar looking devices having a different performance rating. Harmonization in RPD performance is desired by some. ISO has developed a classification scheme based on new RPD performance standards, which if adopted, could result in worldwide harmonization. The classification is different in that the RPD performance level is based solely on the performance requirements and not its design. The performance class is included in the RPD classification.

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The Respiratory System

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4.1 Overview

The primary purpose of the respiratory system is to provide oxygen (O_2) to the cells for cellular metabolism (internal respiration) and to remove carbon dioxide (CO_2) (the major byproduct of cellular metabolism) from the blood (Hirsch 2010, West 2012). This is accomplished through a two-step process. First, ambient air is moved in and out of the lungs. This step is referred to as ventilation. The second step, known as external respiration, is when gas exchange occurs across the semipermeable lung membrane known as the alveolar–capillary membrane.

4.2 Respiratory Anatomy and Function

The respiratory tract is composed of both upper and lower airways. The upper airway contains the nasal cavity, oral cavity, pharynx, and larynx (Figure 4.1). The nasal cavity filters, humidifies, and warms the air entering the body. Here, mucous-lined epithelial membranes are blanketed with hair-like fibers known as cilia which filter the larger sized particles and debris for elimination from the nasal cavity (Martini and Bartholomew 2003). Bony, soft tissue projections (turbinates) create turbulent airflow to humidify and warm the inhaled air. The turbulent airflow also enhances the deposition of airborne particles onto the ciliated mucus membranes for elimination (Kulish 2006). In this way, the nasal cavity effectively filters at least 50% of particles >3–5 μm in diameter (Beachey 2013, Brown et al. 2013). The pharynx extends from behind the nasal cavity to the base of the tongue. It further warms, humidifies, and filters foreign particles. Its mucosal epithelium is lined with lymphatic tissues that defend against potentially infectious pathogens (Beachey 2013). At the base of the tongue lies the cartilaginous larynx which contains the vocal cords whereby sound is transmitted. Along the superior border of the larynx

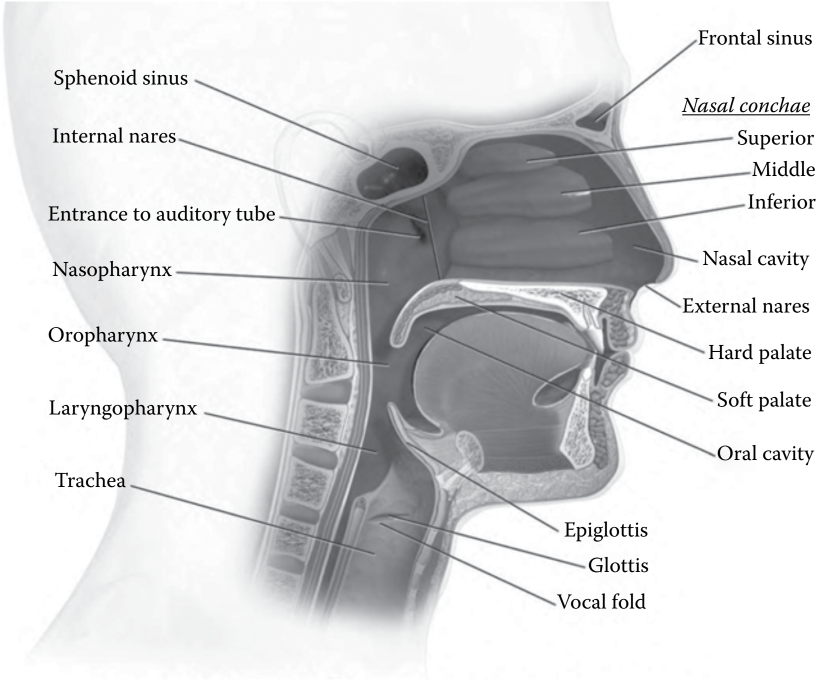
Frontal sinus
Sphenoid sinus
Nasal conchae
Superior
Internal nares
Middle
Inferior
Entrance to auditory tube
Nasal cavity
Nasopharynx
External nares
Oropharynx
Hard palate
Soft palate
Laryngopharynx
Oral cavity
Trachea
Epiglottis
Glottis
Vocal fold

FIGURE 4.1
The upper respiratory system. (Modified from Blausen.com staff. 2014. *WikiJournal of Medicine* 1(2). DOI:10.15347/wjm/2014.010. ISSN 2002–4436. CC BY 3.0.)

extends a muscular extension called the epiglottis that covers the trachea during swallowing (Beachey 2013). The main function of the epiglottis is to prevent aspiration (inhalation) of food particles and liquids (Figure 4.1).

Distal to the larynx lies the lower airway. It consists of a matrix of dichotomously branching tubes that become narrower and more numerous as they extend for 23 divisions or generations into the thorax (West 2012, Beachey 2013). The lower airway consists of two distinct zones: the conducting zone and the respiratory zone (Figure 4.2).

The conducting zone is composed of the first 16 generations of airway branching (Johnson and Hsia 2006, Beachey 2013). It contains the trachea, bronchi, bronchioles, and terminal bronchioles (Figure 4.2). Here, epithelial membranes are ciliated. The cilia beat in the direction of the pharynx to aid in the removal of foreign particles toward the upper airway. The conducting zone does not participate in gas exchange and accounts for the anatomical

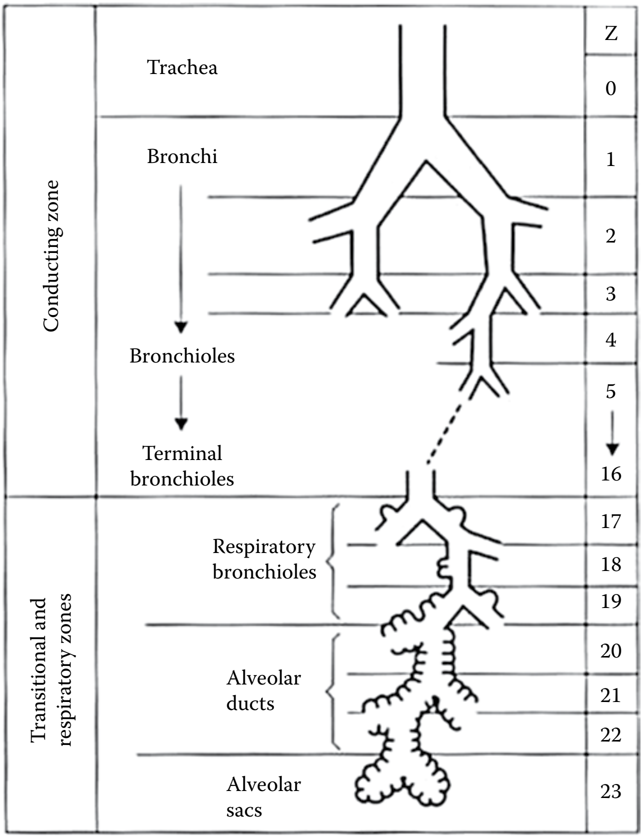
Conducting zone
Trachea
Bronchi
Bronchioles
Terminal bronchioles
Transitional and respiratory zones
Respiratory bronchioles
Alveolar ducts
Alveolar sacs
Z
0
1
2
3
4
5
16
17
18
19
20
21
22
23

FIGURE 4.2
Airway generations of the tracheobronchial tree. (Modified from *The Conductive and Respiratory Zones of the Lungs*. 2.0 Generic. CC BY 2.0.)

dead space of the lower airways (approximately 150 mL per breath in an adult). The primary function of this region is to act as a conduit that moves air into and out of the lungs.

As airway diameters become smaller, the air velocity of the inspired breath is reduced to create laminar flow in preparation for the fragile interface of the alveolar–capillary membrane (Johnson and Hsia 2006). At the terminal bronchioles, the cross-sectional area of the respiratory tract is vastly increased, the velocity of air is minimal, and airways are less than 1 mm in diameter.

In the respiratory zone, each terminal bronchiole feeds into a cluster of several respiratory bronchioles, alveolar ducts, alveolar sacs, and approximately 10,000 alveoli which are collectively known as a primary lobule or acinus (Figure 4.3). Here, gas exchange occurs and each anatomical structure within the acinus has different characteristic features (Costanzo 2010). Within the respiratory bronchioles (16th–18th generations) there is a spattering of alveoli, cilia are sparse, and there is little smooth muscle surrounding the outer wall of the airway (Costanzo 2010, Beachey 2013). Distally, alveolar ducts branch from the respiratory bronchioles as tiny, non-ciliated, alveoli-lined airways (~0.3 mm in diameter). Beyond the alveolar duct extends an alveolar sac containing approximately 16–17 alveoli. Alveolar sacs appear as tiny grape-like clusters of alveoli, each supplied with blood-flow from a pulmonary arteriole, a lymphatic drainage structure, and nerve fibers (Figure 4.3).

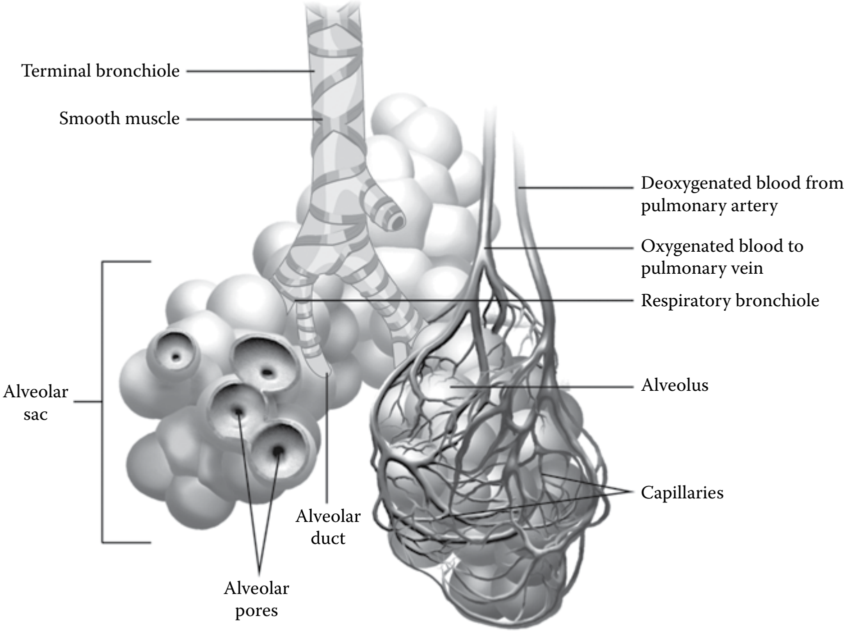
Terminal bronchiole
Smooth muscle
Deoxygenated blood from pulmonary artery
Oxygenated blood to pulmonary vein
Respiratory bronchiole
Alveolar sac
Alveolus
Capillaries
Alveolar duct
Alveolar pores

FIGURE 4.3
Lung acinar unit. (Modified from The Respiratory Zone.jpg. *Illustration from anatomy & physiology*, Connexions Web site. http://cnx.org/content/col11496/1.6, Jun 19, 2013. CC BY 3.0.)

Alveoli are the gas-exchange units of the respiratory system (Beachey 2013). Alveoli are one cell thick and each is surrounded by a network of miniscule pulmonary capillaries. On average, adult lungs contain between 300 and 500 million alveoli with an approximate 0.2 mm mean diameter (Beachey 2013). In total, the lungs provide approximately 100 square meters (m^2) of surface area for gas exchange.

4.3 The Alveolar–Capillary Membrane

The alveolar–capillary membrane is where external respiration or gas exchange between the respiratory and vascular systems takes place. It is roughly 0.5 μm thick and composed of a thin-walled alveolar epithelium and a pulmonary capillary endothelium separated by a thin interstitial space containing extracellular matrix proteins such as collagen and elastin (Figure 4.4) (Costanzo 2010, Beachey 2013). A pulmonary capillary network of approximately 140 m^2 encompasses the alveoli (Figure 4.3). Here, the deoxygenated blood from the tissues comes in close contact with the alveolar membrane. At rest, approximately 5 L of blood (known as cardiac output) passes through the pulmonary capillary bed per minute (Costanzo 2010). This volume can increase significantly during exercise or stress. During exercise, a normal adult's maximum cardiac output is between 14 and 20 L/min. However, trained athletes can achieve cardiac outputs as high as 40 L/min.

Over-accumulation of fine or ultra-fine particles may destroy the integrity of the alveolar–capillary membrane. For example when particle overload occurs,

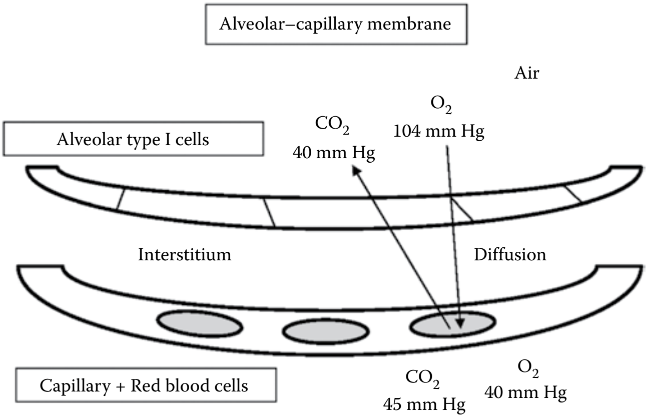

FIGURE 4.4
Alveolar–capillary membrane.

deposition within the interstitium can produce an inflammatory response, whereby, collagen fibers form fibrous connective tissue between alveolar and pulmonary capillary basal membranes (Moller et al. 2010). Inflammatory responses to particles can also destroy normal lung architecture. In either situation, gas exchange across this semipermeable membrane can be impaired.

4.4 Mechanics of Ventilation

The sternum, spinal column, ribs, and dome-shaped muscle called the diaphragm define the boundaries of the thoracic cavity (Revoir and Bien 1997). Breathing is the result of the successive enlargement and contraction of the thorax. During inspiration, the diaphragm and external intercostal muscles (located between each rib) contract to expand the thorax in a "bucket handle" type motion (Chatburn and Daoud 2010). Through this expansion, air pressure in the alveoli becomes lower than atmospheric air pressure, and air flows readily from the nose or mouth into the lungs. At the start of inspiration, the inspiratory flow rate increases from zero and the lungs fill with air; then as atmospheric and alveolar pressures begin to equalize, the flow rate decreases. When equalized, airflow stops and inspiration ceases (Chatburn and Daoud 2010). The diaphragm is the primary muscle of ventilation and accounts for approximately 70% of the change in lung volume during quiet breathing (Kulish, 2006). Other accessory muscles in the neck, thorax, and abdomen contribute to forceful breathing during exercise (Hicks 2010).

Unlike inspiration, which involves active contraction of respiratory muscles, expiration is generally passive. It is a result of the diaphragm relaxing and the natural elastic recoil of the lung (Costanzo 2010, Beachey 2013). Only during forced exhalation, such as during high levels of exercise, respiratory distress, or spirometry testing, do the diaphragm, internal intercostals, and accessory muscles contribute to the compression of the thorax and reduction in lung volume (Hicks 2010).

Breathing consists of a rhythmic cycling of air into and out of the lungs. One breath consists of both an inspiratory phase and expiratory phase. The number of inspirations per minute is known as the respiration rate or breathing rate. The total volume of air expired in 1 minute is known as the minute ventilation. On average, a healthy resting adult breathes between 12 and 16 breaths per minute, with an average minute ventilation of approximately 5–7 L/min (Vincent 1995, Chatburn and Daoud 2010). However, with exercise or strenuous activity, oxygen consumption and CO_2 production can increase 20-fold (Hirsch 2010). Both the rate and depth of breathing will increase to compensate for the increased CO_2 production and O_2 demand of the cells. During strenuous activity, the average maximum sustained ventilation is generally between 90 and100 L/min for a healthy adult (Chatburn and Daoud 2010, Costanzo 2010).

4.5 Control of Breathing

Breathing is normally under unconscious neurologic control and regulated from breathing centers located in the medulla and pons of the brainstem (Costanzo 2010). It is an integrated process whereby chemical and reflex receptors send sensory impulses to modify breathing (Chatburn and Daoud 2010). Nonetheless in lieu of neurologic control, the rate, rhythm, and depth of breathing can be altered consciously, but only for a short period of time (Chatburn and Daoud 2010).

Impulses conducted by the phrenic nerves activate the diaphragm to contract and initiate inspiration (Costanzo 2010). Phrenic nerves arise from spinal nerve branches of the cervical spine between the third and the sixth cervical vertebrae. Spinal cord injury above the third cervical vertebrae can result in diaphragm paralysis and thus, the inability to breathe (Hicks 2010).

Chemical receptors (chemoreceptors) are located in the medulla, aortic arch, and carotid arteries. These receptors help regulate breathing in response to blood plasma and cerebrospinal fluid (CSF) hydrogen ion (H^+) concentrations, arterial carbon dioxide partial pressures ($PaCO_2$), and arterial oxygen partial pressures (PaO_2) (Hicks 2010).

Central chemoreceptors located along the ventral aspect of the medulla are responsive to H^+ concentrations within the CSF (Costanzo 2010). Moreover, CO_2 within the blood readily diffuses across a semipermeable membrane surrounding the brain known as the blood–brain barrier and dissolves within the CSF. Here, dissolved CO_2 instantaneously reacts with water to form hydrogen and bicarbonate ions (i.e., $CO_2 + H_2O \rightarrow H^+$ and HCO^{3-}). This reaction quickly increases H^+ concentrations and stimulates medullary neurons to cause an increase in breathing (Costanzo 2010, Beachey 2013). A small increase in $PaCO_2$ (as little as one millimeter of mercury) can increase alveolar ventilation by as much as 2–3 L/min. Vigorous activity (i.e., increased CO_2 production) can increase ventilation by as much as 10–12 times that of normal resting conditions. Hence, CO_2 levels primarily control breathing (Chatburn and Daoud 2010).

Peripheral chemoreceptors located in the carotid arteries and arch of the aorta monitor both PaO_2 and H^+ concentration (Hicks 2010). Ventilation is increased when blood pH or PaO_2 decrease. However, O_2-sensitive receptors do not have much impact on breathing patterns until PaO_2 levels are significantly decreased. Only when PaO_2 is considerably reduced by conditions such as high altitude, low-oxygen environments, vigorous activity, or disease, do peripheral chemoreceptors stimulate the respiratory centers to increase both depth and rate of breathing (Chatburn and Daoud 2010).

In addition to chemoreceptors, a multitude of sensory reflex receptors send the brainstem information. Positional sensors (proprioceptors) located in muscles, tendons, and joints are important for increased ventilation during exercise. Proprioceptors send sensory information that leads to an increase in both inspiratory volume and rate of breathing (Costanzo 2010). Additionally, stretch reflex receptors are located in the lungs, muscles, and joints. The most recognized of these are the Hering–Breuer stretch receptors located in the smooth muscle of the large and small airways (Beachey 2013). During quiet breathing, these stretch receptors are not stimulated. However, in times of moderate to strenuous exercise or when the tidal volume is increased, this inflation reflex sends information to stop inspiration to prevent over-inflation and excessive stretching of the lung (Chatburn and Daoud 2010). There are still other peripheral reflex receptors that produce reflex impulses for sighs, coughs, or sneezes to protect the respiratory tract from potentially harmful gases, vapors, fumes, and particles.

4.6 Respiratory System Defense

The respiratory system utilizes a number of mechanisms to trap and remove particles. As already noted, upper airway filtering efficiently removes large inhaled particles. However, smaller particles or larger particles inhaled during such activities as strenuous activity or mouth breathing can lead to their advancement into the more distal lower airways (Hicks 2010). Hence, there are several lower airway mechanisms that also effectively trap and remove penetrating particles from the respiratory system.

4.6.1 Mucociliary Escalator

Within the bronchial epithelium lie goblet cells and submucosal mucus glands which blanket the respiratory tract with a continuous layer of mucus. Approximately 0.1 L of mucus is normally produced each day (Hicks 2010). These secretions help to protect the respiratory tract from water loss, shield the epithelial cells from direct contact with potentially toxic substances, and trap airborne particles (Beachey 2013). The epithelium from the trachea to the terminal bronchioles is ciliated (~250 cilia per cell) and each cilium beats at approximately 1000 times per minute in the same direction. The result is a moving sheet of mucus that contains trapped inhaled particles which moves at an approximate rate of 2 cm per minute in the direction of the pharynx (Figure 4.5). This mechanism is known as the mucociliary escalator and the process is known as mucokinesis (Hicks 2010). Chronic exposure to air pollutants or irritant particles can result in submucosal gland hypertrophy and goblet cell hyperplasia. This leads to increased production of mucus to further facilitate the removal of the trapped particles (Figure 4.5).

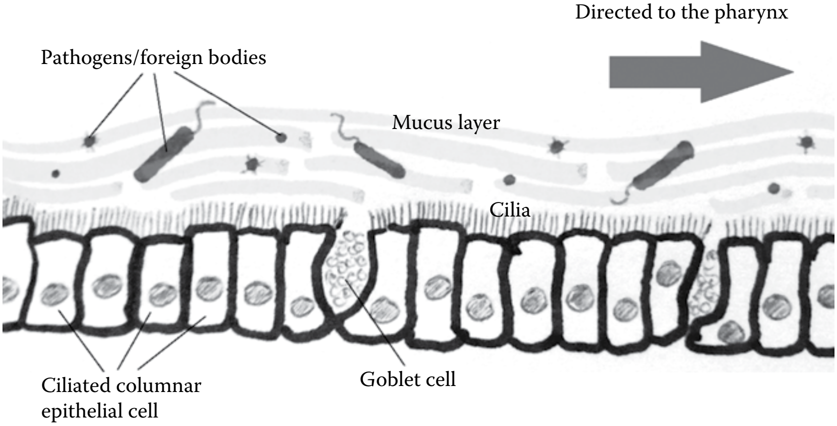

FIGURE 4.5
Mucociliary escalator. (Modified with permission from *Mucociliary Escalator* by J. Aguinaldo. http://mph.sgu.edu/mphblog/2015/11/23/winter-diseases-why-the-cold-makes-us-sick/.)

4.6.2 Cough

Irritant or cough reflex receptors are located in the larynx, trachea, carina (i.e., the bifurcation between the right and left main stem bronchi), and within each main stem bronchi (Hicks 2010). They can be mechanically (particles and dusts), chemically (vapors and fumes), or thermally (cold air) stimulated and are under autonomic parasympathetic nervous system control. When irritant receptors are stimulated, sensory impulses via the vagus nerve are sent to the medullary respiratory centers to produce a cough (Costanzo 2010, Hicks 2010). A cough is a protective mechanism that creates an explosive, forceful, burst of expiratory air. The shearing forces created by the cough expel mucus and foreign particles from the respiratory tract.

4.6.3 Bronchoconstriction

Within the distal bronchi and bronchioles are irritant receptors that, when stimulated, cause airway narrowing known as bronchoconstriction. Here, the smooth muscle fibers that are woven around the external walls of bronchi and bronchioles are stimulated to constrict, preventing potentially harmful substances from penetrating the lungs (Hicks 2010). Bronchoconstriction is an adaptive mechanism, but in diseases such as asthma, these receptors are hypersensitive and can initiate bronchoconstriction when there is no real threat.

Bronchoconstriction can also be induced by J-receptors located within the distal bronchioles, the lung, and adjacent pulmonary vascular capillaries (Beachey 2013). They can be stimulated during cold air breathing, with strenuous exercise, or when pulmonary capillary pressures are abnormally increased. J-receptor stimulation produces rapid shallow breathing, laryngeal constriction, slowed heart rate, and increased mucus secretion (Costanzo 2010, Hicks 2010). Alveolar inflammatory processes caused by inhaled irritant or toxic substances can also stimulate J-receptors.

4.6.4 Alveolar Macrophages

Alveolar macrophages are free-roaming phagocytes that engulf and transport infectious agents or inhaled particulates deposited in the alveoli (Costanzo 2010). They are the primary defense mechanism for the acinus. Upon phagocytosis of a foreign particle, the macrophage can transport it to the terminal bronchioles for mucociliary clearance, migrate and transport it into the interstitium and associated lymphatic vessels, or simply engulf the particle and remain within the alveoli (Costanzo 2010, Beachey 2013). If particles carried to the interstitium are not cleared and are left to accumulate, they can induce pathological responses that damage lung tissue, including the alveolar–capillary membrane (Costanzo 2010).

4.7 Gas Exchange

In the body, gas exchange occurs through simple diffusion, as a result of pressure gradients across semipermeable cell membranes (Hirsch 2010). Oxygen saturated blood is pumped from the left side of the heart and flows through systemic capillary beds to feed each cell in the body. When blood passes through the systemic capillaries, O_2 partial pressures are greater in the blood than in the surrounding extracellular fluid (Figure 4.6). Thus, a pressure gradient exists and O_2 is released by the hemoglobin (Hb) of the red blood cell (RBC), and diffuses across the thin, semipermeable capillary membrane into the surrounding extracellular fluid (Hirsch 2010, West 2012, Beachey 2013). Due to a continued pressure gradient between the extracellular fluid and tissue cells, O_2 then diffuses across the cellular membrane into the cell for its use during cellular metabolism (internal respiration).

Within the cell, CO_2, water, and energy (ATP) are produced from the breakdown of various food substances (Costanzo 2010). At this point, CO_2 partial pressures are greater within cells and CO_2 readily diffuses across the cell membrane, into the extracellular fluid, and across the systemic capillary membrane into the blood. The majority of the CO_2 that crosses the RBC membrane is converted into carbonic acid by the enzyme, carbonic anhydrase (Beachey 2013). The carbonic acid cannot pass through the RBC membrane (Costanzo 2010). Deoxygenated blood, laden with CO_2, is transported to the right side of the heart, and pumped to the pulmonary capillary beds (Figure

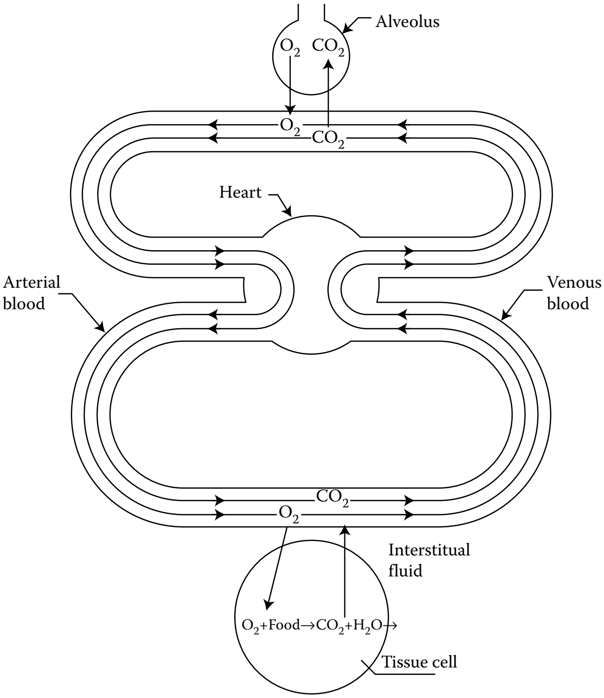

FIGURE 4.6
Transport of O_2 and CO_2 for internal and external respiration. (Copyright 1997 from Revoir, W. H. and C. T. Bien. 1997. In *Respiratory Protection Handbook*. Boca Raton, FL: CRC Press/Taylor & Francis. Reproduced by permission of Taylor and Francis Group, LLC, a division of Informa plc.)

4.6). Here, the carbonic acid trapped in the RBC undergoes a reverse reaction to form diffusive CO_2 (Beachey 2013).

At the thin alveolar–capillary membrane, gaseous partial pressure gradients between the alveoli and blood within the pulmonary capillaries allow for simple diffusion of O_2 into the blood and the release of CO_2 from the RBC. CO_2 readily diffuses across the alveolar–capillary membrane and diffuses into the alveolus for elimination (external respiration) (Hirsch 2010, Beachey 2013). It is a coordinated process whereby release of CO_2 from the Hb molecule augments the uptake and binding of O_2 onto the Hb molecule (Bohr effect); and the attachment of O_2 facilitates Hb release of CO_2 (Haldane effect) (Costanzo 2010). Any thickening of the alveolar–capillary membrane due to injury or disease can impede the diffusion of CO_2 and O_2.

Not all air entering the respiratory system partakes in gas exchange. Approximately two-thirds of minute volume is actually available for gas exchange and this volume is referred to as the alveolar minute ventilation (VA) (Ruppel 2009). The remaining one-third of the respired volume remains in the conduction zone of the respiratory tract.

4.8 Particle Deposition

Factors such as breathing pattern (mouth vs. nose), tidal volume, velocity of airflow (resting vs. exercise), airway morphology, age, sex, and race can influence the deposition of inhaled particles along the respiratory tract (Bennett and Zeman 2005, Kuempel et al. 2015). In general, when the velocity of airflow is held constant but tidal volume is increased, a greater proportion of particles are able to be deposited in the more distal airways (Sturm 2011). Mouth breathing and increased velocities also allow more distal particle deposition (Figure 4.7).

Respiratory tract particle deposition is primarily determined by a particle's aerodynamic diameter. During normal breathing, the current ambient and occupational 50% thoracic fraction particle cut-size is conventionally considered to be approximately 10 μm in aerodynamic diameter. However, more recent research suggests that the 50% ambient particle thoracic fraction cut-size is closer to 3–5 μm; with less than 20% penetration of 10 μm sized particles into the lower airway (Brown et al. 2013). Inertial impaction is the mechanism responsible for the greatest proportion of deposition along the epithelial surface of the upper airways (Sturm 2011). Inertial impaction also accounts for the deposition of particles >1.5 μm in diameter at airway branches within the airway conduction zone. Additionally, particle sedimentation or settling occurs through gravitational forces for particles >0.5 μm in aerodynamic diameter.

Within both the tracheobronchial and acinus regions, minimal fine particle deposition is reached at diameters of approximately 0.4–0.5 μm (Figure 4.7) (Moller et al. 2010, Kuempel et al. 2015). As airflow velocity decreases, smaller and smaller particles are transported into the more distal airways independent of gravitational forces. Here, a process known as Brownian diffusion increases with decreasing particle size (Figure 4.7). This process is where particles are deposited along the epithelium due to random motion and collision with gas molecules. Within the acinus, Brownian diffusion becomes the dominant deposition process for particles <0.3 μm and peaks at particle sizes with diffusion diameters of $\sim$0.01 μm (Kuempel et al. 2015). Along the alveolar surface, these ultrafine particles are phagocytized by alveolar macrophages and dendritic cells.

Nano-sized particles between 1 and 100 nm are most effectively deposited at the gas-exchange regions of the lung but they are not as readily phagocytized by alveolar macrophages (Moller et al. 2010). In addition to particle size, characteristics such as shape, electrostatic potential, or hydroscopic forces also affect deposition. Nanoparticles are often translocated into the epithelial tissue, interstitium, pulmonary endothelium, or even into secondary organs. Translocation refers to the process whereby particles migrate across at least one semipermeable membrane. Translocation of inhaled nanoparticles into or across pulmonary epithelium is usually rapid (1–2 days) and dose dependent (Moller et al. 2010). Moreover, nanoparticle translocation rates vary based on particle size, surface charge, and surface composition.

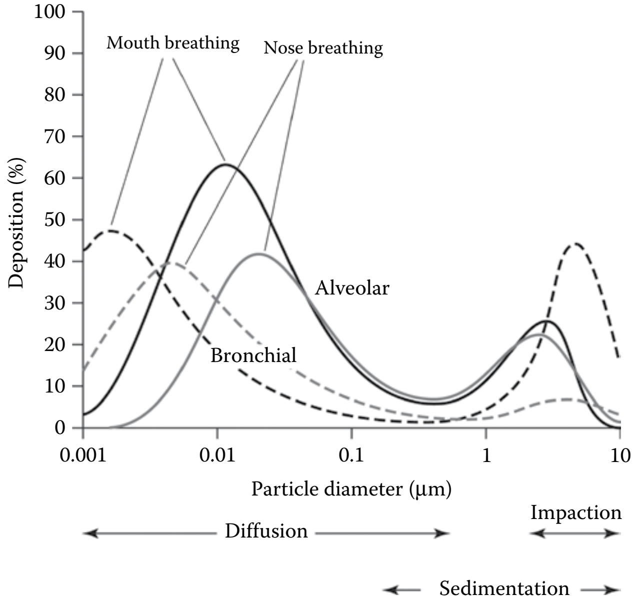

FIGURE 4.7
Bronchial (dotted lines) and alveolar (solid lines) particle deposition within the human respiratory tract based on particle diameter according to ICRP Publication 66. Data are shown for two different labeled breathing scenarios: (1) Nose breathing and (2) mouth breathing. The arrows indicate the particle diameter regime of the different deposition mechanisms in the respiratory tract. (Copyright 2010 from Moller, W. et al. 2010. In *Particle-Lung Interactions*, 2nd Edition, eds. P. Gehr, C. Muhlfeld, B. Rothen-Rutishauser and F. Blank, 79–108. New York: Informa Healthcare USA, Inc. Reproduced and modified by permission of Taylor and Francis Group, LLC, a division of Informa plc.)

Upon translocation and secondary deposition, nanoparticles are not easily cleared through conventional immunological clearance mechanisms (Moller et al. 2010). Therefore, they have potential to accumulate and overwhelm homeostasis to cause chronic inflammation or disease in distal organs. However, they have also been used to function as carrier particles in medical research to target secondary organs in diseases such as cancer.

4.9 Lung Volumes and Capacities

The volume of air that an individual can inhale or exhale is classified into specific lung volumes and capacities (Ruppel 2009). The total volume of air that the lungs contain following a maximal inspiration is known as the total lung capacity (TLC). On average, a healthy 20-year-old Caucasian male will have a 6 L TLC (Figure 4.8). However, lung volumes vary with height, race, sex, age, and degree or type of ventilatory impairment. In general, taller people have larger lungs because the lungs grow in proportion to the thoracic cage. Men tend to have larger lungs than women of the same height, race, and age. African-American and Asian-Americans tend to have smaller lungs than Caucasian Americans of the same sex, height, and age. Lastly, lung volumes continue to increase from birth into the early adult years (Ruppel 2009). After reaching maximum values in early adulthood, there is a subsequent decrease over time.

There are four lung volumes: (1) Tidal volume (TV); (2) inspiratory reserve volume (IRV); (3) expiratory reserve volume (ERV); (4) residual volume (RV) (Figure 4.8). TV represents the volume of air contained within a resting breath. The average TV is approximately 0.5 L and represents approximately 8% of the TLC.

The depth of any breath can be altered under voluntary control or when there is increased ventilatory demand, such as during strenuous activity (Costanzo 2010). The IRV represents the amount of air that can be maximally inhaled following the inspiratory phase of a TV. The ERV is the volume of air that can be forcefully exhaled following the expiratory phase of a TV (Figure 4.8). The portions of the lung that represent these lung volumes are recruited when breathing depth is increased as seen during strenuous activity. Recognize that the lungs are never completely emptied of air, even at the end of a maximal expiration. This is caused by the opposing expansion

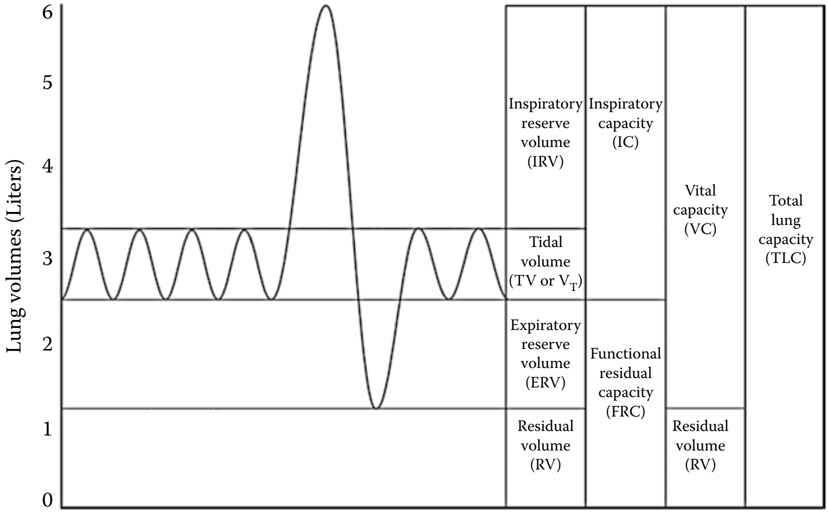

FIGURE 4.8
Spirogram of lung volumes and capacities from a classical 20-year-old Caucasian male model. (Modified from *Lung Volumes Updated*, Kapwatt, https://en.wikipedia.org/wiki/File:Lungvolumes_Updated.png. CC BY 3.0.)

force of the rigid thorax, and is known as the RV. Approximately 20% of TLC (1.2 L) remains within the lungs at RV (Ruppel 2009, Beachey 2013).

Lung volume classification also includes four distinct lung capacities. Capacities describe the maximal volume of air that can be obtained based on a specific breathing maneuver. Thus, volumes are dynamic values that reflect neural control, whereas, capacities tend to reflect anatomical limitations of the respiratory system. Two or more lung volumes are combined to form a lung capacity (Cotes et al. 2006, Ruppel 2009).

TLC combines all four of the lung volumes (Figure 4.8). The volume of air that can be exhaled from maximal inspiration to maximal exhalation is termed the vital capacity (VC). This volume measurement is often used during pulmonary function testing (Ruppel 2009). The functional residual capacity (FRC) represents the air contained in the lungs following the passive exhalation phase of a TV. The inspiratory capacity (IC) is the volume contained within a maximal inspiration from a resting end-expiration or FRC. Lung capacities can also be identified by their component volumes:

$$\mathrm{TLC} = \mathrm{RV} + \mathrm{ERV} + \mathrm{TV} + \mathrm{IRV}$$

$$\mathrm{VC} = \mathrm{ERV} + \mathrm{TV} + \mathrm{IRV}$$

$$\mathrm{FRC} = \mathrm{ERV} + \mathrm{RV}$$

$$\mathrm{IC} = \mathrm{TV} + \mathrm{IRV}$$

An individual's lung volumes or capacities can be chronically reduced or increased based upon the presence of respiratory disease (Cotes et al. 2006, Ruppel 2009).

4.10 Spirometry

Initial screening of basic lung function is often assessed by spirometry, a breathing test that, if performed by well-trained technicians and interpreted by qualified physicians, can establish an accurate baseline for workers and reveal longitudinal changes indicative of ventilatory impairment or respiratory disease (ATS/ERS 2005). Spirometry measures the volume of air that can be maximally and forcefully exhaled from TLC. It should be emphasized that during spirometry, the exhalation must be forced in order to obtain accurate measurements (Cotes et al. 2006, Ruppel 2009). This is known as a forced vital capacity (FVC). Theoretically, FVC is the same as VC, but in reality the FVC is often slightly less than VC volume. This is a result of a small airway closure with air trapping that is often seen following a forced expiratory maneuver (Ruppel 2009).

The maximum amount of air that can be forcefully exhaled in 1 second from TLC is known as the forced expiratory volume at 1 second (FEV1). The ratio between FEV1 and FVC is indicated by FEV1/FVC. This ratio is critical for spirometry interpretation (ATS/ERS 2005, Cotes et al. 2006).

Spirometry assesses two basic concepts of lung function, each comprised of many influencing factors. The first is ease of lung expansion, termed compliance (Δ volume/Δ pressure). When compliance is abnormally reduced, the lungs are unable to expand to their maximum volume due to a restrictive influence. As a result, the FVC may be reduced. Some causes include tumors, interstitial fibrosis, obesity, and weakness of respiratory muscles (such as from neuromuscular disease) (Ruppel 2009).

The second concept, airway resistance, affects forced exhalation when the diameter of conducting airways is reduced, obstructed due to bronchoconstriction, or blocked due to inflammation and mucus (Lumb 2010, Ruppel 2009). Obstruction can also be related to small airways collapse. Unlike the larger airways, the smaller airways (at approximately the 11th generation) have no system of cartilage ring reinforcement and are susceptible to collapse during forceful breathing (Lumb 2010). When airway obstruction is present, the speed of exhalation is slowed and airway resistance is increased. Hence, the measurement of FEV1 is reduced compared to FVC and the ratio (FEV1/FVC) becomes abnormally low. Possible causes include asthma, chronic bronchitis, or chronic obstructive pulmonary disease (COPD).

Spirometry testing may be performed for diagnostic purposes, worker health surveillance, public health surveys, or for disability screening. Worker surveillance programs often include pre- and post-shift, cross-sectional, or longitudinal (often annual) spirometry testing. It is important to assure minimal variability in equipment, technique, time of year and day, and subject position, especially when a worker's lung function is followed over time (ATS/ERS 2005).

Volume-type spirometers are an older technology that is now uncommon. They directly measure exhaled volume over time via a collecting apparatus (Ruppel 2009). Recent spirometers measure air speed (flow) over time through various technologies with indirect calculation of volume as the product of flow versus time. These are called flow-type spirometers. Either method of measurement technique requires adherence to published minimum standards and guidelines. Reference publications include the "Standardisation of Spirometry" (ATS/ERS 2005); "Spirometry in the Occupational Health Setting, 2011 Update" (Townsend 2011); and "Spirometry Testing in Occupational Health Programs, Best Practices for Healthcare Professionals" (OSHA 3637-03 2013).

Spirometry technicians who administer the test, play a critical role in assuring that tests are valid and of high quality. Technicians should undergo practicum training to adequately coach those being tested, and correct errors caused by issues in subject or equipment performance. An understanding of the basic physiology of the FVC maneuver and resultant spirometry outcomes is also important. Requirements published by the Occupational Safety and Health Administration (OSHA) in the cotton dust standard (OSHA 29 CFR 1910.1043 Appendix D 1978), state that technicians who perform spirometry under the Standard, should have approximately 16 hours of formal instruction. The NIOSH Spirometry Training Program was initiated in order to certify instructional programs in spirometry training. Studies have shown that performance improves when spirometry technicians are properly trained and provided with ongoing feedback about the technical quality of the tests they perform (Eaton et al. 1999, Carr et al. 2011, Seyedmehdi et al. 2013).

In summary, the respiratory system is a complex, integrated system that provides a functional interface between the atmosphere and internal physiologic processes. Innate protective mechanisms help to preserve homeostasis; however, these mechanisms can be overcome depending upon the amount and type of exposures. Therefore, it is important to both properly protect and monitor lung function in persons environmentally exposed to toxic, irritant, or pathogenic respirable substances.

Disclaimer

The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the National Institute for Occupational Safety and Health.

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5

Speech Intelligibility during Respirator Wear

Karen M. Coyne and Daniel J. Barker

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5.1 Introduction

The ability to communicate effectively with colleagues and the public is critical for law enforcement officers, fire fighters, and medical personnel. Due to their unique mission requirements, these personnel must sometimes wear respiratory protective equipment (RPE). This RPE may be a filtering facepiece respirator (FFR), full facepiece air-purifying respirator (APR), half-facepiece elastomeric APR (EAPR), or self-contained breathing apparatus (SCBA) facepiece. Speech intelligibility is the primary performance criterion used to assess the quality of speech sound transmission through a respirator's speech transmission components.

There are both objective and subjective methods of assessing speech intelligibility, each of which has advantages and disadvantages. An objective test does not measure intelligibility directly. Rather, it measures select sound quality parameters and predicts intelligibility based on those parameters. Subjective tests use human subjects directly to gauge intelligibility.

5.1.1 Speech Intelligibility Tests

5.1.1.1 Modified Rhyme Test

Commercial respirators are certified by the National Institute for Occupational Safety and Health (NIOSH). The NIOSH APR chemical, biological, radiological, and nuclear (CBRN) standard (2005) assesses speech intelligibility during respirator wear by scores resulting from the modified rhyme test (MRT) (House et al., 1965). This is a subjective test that evaluates a listener's ability to identify single monosyllabic words spoken by a respirator wearer. A major drawback of the MRT procedure is the time and cost required to conduct the test. In addition, the test participants must be attentive and motivated. Five speakers and three listeners are required to complete the test. Test speakers must speak without a noticeable or strong regional accent and are required to maintain a sound output level between 75 and 85 dB when not wearing a respirator, and then duplicate the same vocal effort while wearing a respirator. As the respirator alters the sound level, there is no way to assess whether the words are being spoken with the same intensity. If all the speakers consistently speak at 75 dB, the performance rating (PR) of the mask might be lower than if an 85 dB sound level were maintained. Speakers may also over-enunciate words while wearing the mask, further altering the sound signal. While scores are averaged across speakers, it is possible that one very bad speaker could cause a respirator that should have passed to result in a failed test. Because this is a subjective test, results depend on the subject responses and cannot be reproduced exactly.

5.1.1.2 Speech Transmission Index

The National Fire Protection Association (NFPA) 1981 standard (2013) switched from the MRT to a simplified version of the speech transmission index (STI) (Houtgast and Steenegan, 1971) for testing respirator communications. The full version of the STI is not available to the public, so the STI for public address (STI-PA) systems are used instead. The STI-PA is a subset of the STI and is used to decrease the time required to complete the full STI. The STI-PA uses 12 data points that are weighted depending on the psychoacoustic speech model (Sell, 2011). The STI-PA is conducted in a semi-anechoic chamber using a mannequin with a simulated mouth, a microphone, and a pink noise generator and speaker. The respirator system is donned on the mannequin. The mouth simulator transmits a modulated noise signal that is representative of speech. A microphone is placed 1.5 m from the mannequin to receive the speech signal. Background pink noise is emitted from a speaker placed beneath the microphone. The signal received at the microphone is then analyzed to determine the STI-PA. The STI-PA provides a single score that ranges from 0 (unintelligible) to 1 (excellent intelligibility).

The STI-PA takes less time to administer than the MRT and has the additional benefits of being repeatable and not requiring human test subjects. However, there are also drawbacks to using this method. Positioning of the respiratory protective device on the mannequin could vary from test to test and from operator to operator. The microphone does not represent human binaural hearing and does not mimic potential sound localization effects caused by a respirator, hood, or other equipment that would be worn by a listener. The STI-PA cannot take into account respirator created noise (e.g., breathing noise, regulators), the noise created by a hood on the speaker (e.g., rustling), or the impact of a hood on sound reception by the listener. For SCBA, Sell (2011) states that rattling of the second stage regulator due to it not being pressurized can lower STI by six points. Rattling of inhalation and exhalation valves can decrease STI by an additional five points (Sell, 2011). STI scores can vary by 25% depending on the set up (Sell, 2011).

A better understanding of the relationship between STI and MRT would be beneficial to researchers, manufacturers, and respirator wearers. However, few studies investigating the relationship have been published. Griffin (1992) investigated the relationship between MRT and STI in simulated cockpit ambient noise and in pink noise. The author found that the MRT scores were significantly different between the two noise conditions. The author also stated that the MRT and STI yielded approximately the same values. The conference abstract did not include any other results and no other reports were located. NIOSH provided funding (Grant #R01-OH-008-669) for research investigating the relationship between the MRT and STI, but only a conference abstract (Yu et al., 2010) could be found and no results were included. However, in a subsequent article, Brammer et al. (2014) stated that a relationship was developed between the STI and MRT mean word scores. The article further states that the MRT word score can be predicted by the STI. However, the relationship was not provided and no additional information was found.

5.1.1.3 Articulation Band Correlation MRT

Voran (2013) developed an automated speech recognition test that he named the articulation band correlation MRT (ABC-MRT). Voran speculated that automatic speech recognition (ASR) systems could be used to estimate speech intelligibility since ASR performance decreases if speech is impaired. Using this approach would require that ASR errors were consistent with human errors. Voran worked with four sets of impaired speech recordings of the MRT. The method correlated the pattern for an impaired speech signal with the patterns for six unimpaired word options for each of the 50 words in an MRT list. The resulting Pearson correlations were between 0.95 and 0.99. A test method using an ASR similar to the ABC-MRT may provide a bridge between the subjective and purely objective speech intelligibility test methods. However, this ASR needs to be tested with additional respirators to determine how well it would predict intelligibility using respirators and degraded speech recordings it had not previously experienced.

5.1.2 Evaluation of Tests

Several studies have investigated the impact of respirators on speech intelligibility using either the MRT or the STI. Radonovich et al. (2010) tested various half-mask FFR and EAPR and found that MRT ranged from 73% to 91% for a speaker listener distance of 1 m. The MRT scores for the FFR without exhalation valves (88%) did not differ statistically from the control (92%). The EAPR scored significantly lower at 73%.

Coyne and Barker (2010) investigated 12 APR using the NIOSH MRT test procedure (2005). Results from that test procedure provide a PR rather than the MRT score. The PR compares task performance of an individual wearing a mask to the no mask condition. Thus, the no mask condition is used as a baseline reference to more accurately represent the performance decrement due to mask wear. PR measured for each respirator was: MSA Millennium (91%), 3M FR-M40 (88%), MSA Ultra Elite (87%), Scott Safety M110 (86%), North 5400 (85%), Scott Safety M120 (85%), Avon C50 (84%), Avon FM12 (84%), Survivair Optifit (81%), Draeger CDR 4500 (81%), Peltor-AOSafety M-TAC (79%), and 3M FR-7800B (78%). The Millennium and FR-M40 had statistically significantly higher scores than the FR-7800B. The Millennium also scored significantly higher than the M-TAC. Coyne and Barker (2015) conducted a modified version of the NIOSH MRT to determine if an experienced speaker would induce higher, less variable intelligibility scores. The PR with the experienced speaker (86.5% ± 0.6%) were significantly higher than those for the standard method (84.0% ± 0.6%). However, a large variability in listener performance remained.

Symons (2012) investigated the STI-PA for one facepiece, the Scott Safety AV3000. The author found that the test was highly repeatable and that setup and test time were less than for an MRT. The STI-PA values for the facepiece ranged from 0.51 to 0.57. Palmiero et al. (2016) investigated FFR and half-mask EAPR using a modified STI-PA. The authors reported that the STI-PA had less variability than that reported in Coyne and Barker (2010) for the MRT. The FFR (STI-PA = 0.715) had less of an impact on intelligibility than the EAPR (0.465). Interestingly, the EAPR half-mask had more impact on speech intelligibility than the full respirator facepiece evaluated in Symons

(2012). The EAPR tested by Palmiero et al. (2016) was soft rubber while the Scott AV3000 has a large polycarbonate (PC) lens. It is possible that the PC lens transmits the STI-PA signal better than the rubber of the EAPR. Further testing would need to be conducted to assess this theory.

Hollman et al. (2011) provided STI-PA and sound pressure level (SPL) data on six SCBA respirator facepieces, though the manufacturer and model names were not included. SPL was provided at distances of 1.5 and 3 m while STI-PA was provided for at the same distances, but with either no background noise or 60 dBA pink noise. Pink noise was played from the mouth simulator at a level that resulted in a SPL at the microphone of 75 dBA at 1.5 m. The results showed that each of the SCBA caused a decrease in the SPL. Rank order of the SCBA facepieces for 1.5 m was F, C, D, B, A, E for least to greatest effect of the SCBA on sound level. At 3 m, rank order was C, A, F, and a tie between B and E. Data for SCBA "D" were not provided at 3 m. So, increasing the distance at which the SPL was measured changed the rank order. SPL measured for SCBA facepieces A, C, and E showed very little dependence on distance while F had approximately a 6 dBA decrease in SPL going from 1.5 to 3 m. STI at 1.5 m with no background noise ranked the respirators as F, A and C, D and E, and B. At 3 m with no noise, the ranking was F, E, C, B, and A (with no data reported for D). For 1.5 m with 60 dBA background noise, the order was F, D, A and E, C, and B. For 3 m with 60 dBA background noise, the ranking was F, E, A, B, and C, with no data for D. SCBA A showed no decrease in SPL with an increase in distance, but STI decreased by 26%. SCBA E also showed no impact of distance on SPL and STI decreased by 5% with no background noise. SCBA facepieces A and E had approximately a 50% decrease in STI for a distance of 1.5 m when pink noise was added. SCBA F showed a 10% decrease in STI with increasing distance with no background noise, but a 45% decrease in STI when background pink noise was added. So, facepiece F showed the greatest impact of distance, but the least impact of the background noise.

The relationship between the STI-PA and the MRT remains uncertain. Also, the MRT has not been modified to address the subjectivity inherent in the test method. The U.S. Army Edgewood Chemical Biological Center (ECBC) at Aberdeen Proving Ground, MD pursued two efforts related to these two issues. The first effort regarded the utilization of prerecorded speech that may eliminate inconsistencies among speakers. With prerecorded speech, the conduct of the MRT would be easier logistically and would be less costly as only three subjects (listeners) would be required. Less time would be required to complete the test as speaker training would not be necessary. The American National Standards Institute (ANSI) communications standard (1999), on which the NIOSH standard is based, allows prerecorded speech. Also, to better understand the relationship between the MRT and STI-PA tests, it would be helpful to perform STI-PA tests on the 12 APR for which MRT has been previously reported. However, the STI-PA requires specific equipment and software that was not available to ECBC for this effort.

But, acoustic equipment was available to obtain the frequency response of a pink noise signal transmitted through a respirator to a microphone.

5.1.3 Objectives

The first objective of this effort was to determine if using an automated speaking headform in place of a human speaker would impact MRT scores or the variability in results. The second objective was to measure sound levels through previously tested respirators for which MRT was available and to see if there was a correlation between the sound levels and the MRT scores.

5.2 Methods

5.2.1 MRT Trials with Automated Speaking Mannequin

5.2.1.1 Volunteers

Volunteers were recruited from the civilian workforce of the U.S. Army ECBC. The test protocol was approved by the institutional review board at ECBC. All participants completed the Occupational Safety and Health Administration respirator medical evaluation questionnaire. A medical professional reviewed the questionnaires and determined that there were no contraindications for respirator wear. Each of the three volunteers (two female, one male; 25.0 ± 4.6 years) gave written informed consent prior to participation in the study. All volunteers were native speakers of American English and passed the hearing test specified in the NIOSH test procedure (2005).

5.2.1.2 Equipment

The equipment used corresponded to that listed in the NIOSH standard (2005) and was the same as that used in previous studies (Coyne and Barker, 2010, 2014, 2015). In brief, a stereo amplifier, two loudspeakers, and a pink noise generator (Bruel and Kjaer Type 1405, Naerum, Denmark) were used to transmit pink noise at 60 ± 2 dBA. The background noise levels were measured at the position of the listener's ear. The A-weighted fast response setting was used on the sound level meters (Model 322, Center Technology Corporation, Taipei, Taiwan). The meters were calibrated at the start of each test day. A Body Opponent Bag (BOB) (Century Martial Art Supply, LLC, Oklahoma City, OK) was modified, during a prior research effort, to create a speaking mannequin (Li Creative Technologies, Florham Park, NJ) by inserting a mouth simulator (Bruel and Kjaer Type 4227) inside the mouth of the BOB (Li et al., 2009). Recordings of MRT stimulus words were also obtained under that same effort. A carrier phrase was later recorded in an

ECBC anechoic chamber. The carrier phrase was placed before each stimulus word using Sony® Sound Forge software (Tokyo, Japan). The software was also utilized to edit time between word and carrier phrase presentations and in turn generate word lists for MRT trials. The speech recordings were saved on a laptop computer. The sound output from the laptop was connected to an amplifier and then to the speaker wires of the BOB speaking mannequin.

Two NIOSH-certified CBRN APRs were used during the human subject and automated speaker trials. The respirators were the 3M FR-7800B (3M, St. Paul, MN) and the MSA Millenium (Mine Safety Appliances Company, Cranberry Township, PA) (Figure 5.1). These were selected because they had the highest and lowest MRT PR in the prior research.

5.2.1.3 Test Procedures

All testing was conducted in the ECBC Respiratory Protection Branch's Individual Protective Equipment Test Facility. The trials followed a modified version of the NIOSH MRT communications certification procedure. Deviations from the standard test procedures were: each volunteer served as both a speaker and a listener; the listener panels consisted of two volunteers for the human speaker trials and three subjects for the automated speaker trials rather than one female and two males; only three speakers were used, one male and two female; and the speaker read one of 12 word lists while wearing each of two masks and one additional word list without the respirator to the same panel of listeners. The mask condition was the same for both the speaker and the listeners. A respirator was placed on the speaking mannequin for trials during which the listeners wore a respirator.

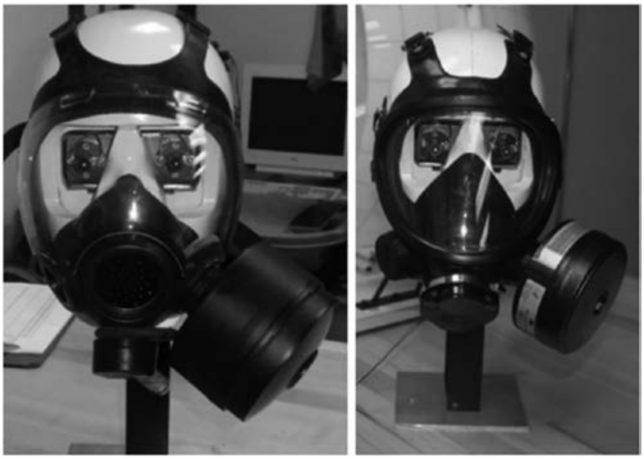

FIGURE 5.1
Respirators used during the automated speaker intelligibility trials. The MSA Millenium is on the left, and the 3M FR-7800B is on the right.

The MRT trials consisted of a test speaker seated directly opposite the listeners at a distance of 3 m. The listeners were positioned before a computer monitor that was used to input responses to the speaker's word presentation. The MRT test required the speaker to read aloud 50 stimulus words to a listener without using any visual signals (e.g., hand motions). The speaker was instructed to say the stimulus words at a constant pace and to keep his or her voice at a constant level throughout the trial. Speakers were trained to read the word lists with a speech sound level between 75 and 85 dBA as measured by a sound level meter positioned approximately 30 cm in front of the speaker's mouth. Each stimulus word was presented with the carrier phrase "The word is _______." The listener was presented six possible answers for each stimulus word and was instructed to select the word that they perceived to be spoken by the test speaker. The NIOSH MRT procedure allows the talker's speech volume to be between 75 and 85 dBA. To investigate the impact of this wide sound level range on MRT results, control no mask trials of one word list each were completed with the BOB speech volume at approximately 75 dBA (BOB low) and at 85 dBA (BOB high). Two word lists were spoken with each respirator on the BOB for both 75 and 85 dBA. In addition, each volunteer read one word list to the other two volunteers for each respirator condition.

5.2.1.4 Data Analysis

MRT scores were adjusted to account for guessing and PR were calculated for each subject according to the NIOSH procedure. Mean speaker output and background noise levels were then determined.

A one-way analysis of variance (ANOVA) test was performed using SigmaPlot 12.0 (Systat Software, Inc., San Jose, CA) for both the background noise and the speech sound levels. ANOVA on ranks was used whenever the ANOVA failed either the normality or equal variance tests. Post-hoc comparison tests were run when a difference was detected by the ANOVA or ANOVA on ranks. The post-hoc test used was the one recommended by the software. A one-way ANOVA on MRT scores was used to determine if there was a difference in the three control conditions for the human speakers, BOB high (85 dBA), or BOB low (75 dBA). A one-way ANOVA was performed to determine if there was a difference in PR based on the high versus low BOB trials. A two-way ANOVA was used to determine if the PR differed based on the factors respirator (Millennium and FR-7800B) and speaker type (human and BOB high).

5.2.2 Pink Noise Tests

5.2.2.1 Equipment

The same automated speaking headform, pink noise generator, sound level meter, and amplifier were used for the pink noise trials. An anechoic

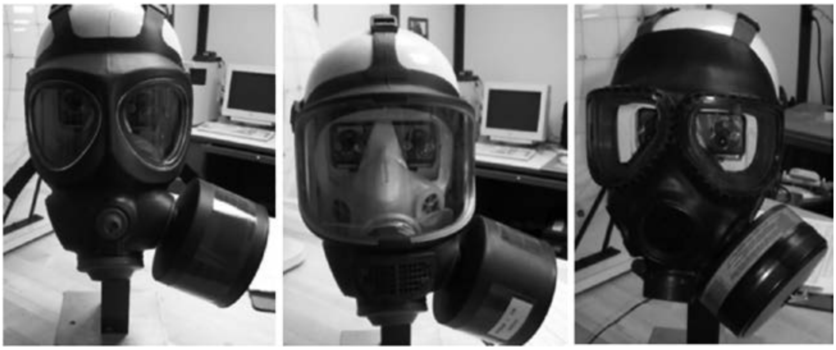

FIGURE 5.2
Additional respirators used for the pink noise trials. (From left to right, the respirators are the Scott M110, Scott M120, and 3M FR-M40.)

chamber, a free field microphone (Type 40AF, G.R.A.S., Denmark) with a power supply (Type 12AK, G.R.A.S., Denmark), a data acquisition (DAQ) board (NI-PCI-4461, National Instruments, Austin, TX), and custom software created in Labview 8.6 (National Instruments, Austin, TX) were also used. Detailed descriptions of the DAQ and software are included in Eshbaugh and Barker (2010). The anechoic chamber measured approximately 3 m × 3 m × 2 m. The microphone was positioned 1 m directly in front of the simulator at the height of the simulator's mouth. The microphone power supply, DAQ, and computer were located outside of the anechoic chamber. The software sampled the SPLs at 50 KHz, calculated the decibel levels in 1/3 octave intervals from 50 to 10,000 Hz, and displayed and stored the results. Five NIOSH-certified CBRN APRs were used in this portion of the study. The respirators included the 3M FR-7800B and the MSA Millennium used for the speaking mannequin trials in addition to the 3M FR-M40, Scott M120 (Scott Health and Safety, Monroe, NC), and Scott M110 (Figure 5.2).

These respirators were selected to cover the range of MRT scores from the human subject testing completed previously with 12 respirators (Coyne and Barker, 2010). The FR-M40 and Millennium had the highest MRT scores, the FR-7800B had the lowest MRT score, and the two Scott respirators had MRT scores in the middle of the range. A control condition was included for which no mask was placed on the mannequin.

5.2.2.2 Test Procedure

The sound level meter and microphone were calibrated prior to each set of trials. Control trials were completed first. The output from the pink noise generator was played through the mouth of the headform at 70 dBA, measured 30 cm in front of the mouth. The operator closed the door to the anechoic chamber and then started the computer software. The sound received at the microphone was recorded for approximately 30 s and processed using the custom software. The operator then opened the door to the chamber, placed one of the respirators on the headform, closed the door, and recorded and processed the SPLs. This process was repeated for the four additional respirators. On subsequent test days, the pink noise generator was set to 75 and 80 dBA and the entire procedure was repeated. No background noise was used in any of these trials. Background sound levels inside the anechoic chamber were not recorded during this effort. A prior unpublished pilot test effort did collect the background noise using the same test equipment. The SPL was 18.3 dBA. The binned frequency data from that prior effort were included as a reference.

5.2.2.3 Data Analysis

SigmaPlot 12 was used for all statistical analyses. The data were inverse log transformed and the average determined of roughly the middle 10 s of the recording. The data were then log transformed back to dBA units. Plots were obtained for the average sound levels versus frequency for each respirator for each of the three noise conditions. In addition, the MRT scores from the prior research effort (Coyne and Barker, 2010) were plotted versus total band power (TBP) for each of the pink noise conditions. A one-way ANOVA was performed to determine if the TBP differed among the respirators for each of the pink noise sound levels. Linear regression equations were determined or each of the MRT plots.

5.3 Results

5.3.1 Automated Speaker Trials

The normality test failed for the ANOVA for both background noise levels, so ANOVA on ranks was used. It showed that the background noise was not different among the mask conditions control BOB high (60.2 ± 0.5 dBA), control BOB low (60.5 ± 0.6 dBA), control humans (60.2 ± 0.6 dBA), Millennium humans (60.3 ± 0.6 dBA), Millennium low (60.6 ± 0.8 dBA), Millennium high (60.3 ± 1.6 dBA), FR-7800B humans (59.9 ± 0.5 dBA), FR-7800B low (61.2 ± 0.4 dBA), and FR-7800B high (59.7 ± 1.8 dBA). The equal variance test failed for the ANOVA for the speech sound levels, so ANOVA on ranks was used. The ANOVA on ranks showed that the speaker noise was different among the conditions: control BOB high (83.6 ± 0.9 dBA), control BOB low (77.2 ± 0.2 dBA), control humans (81.4 ± 2.1 dBA), Millennium humans (79.2 ± 1.9 dBA), Millennium low (70.7 ± 2.8 dBA), Millennium high (79.6 ± 4.9 dBA), FR-7800B humans (80.0 ± 2.8 dBA), FR-7800B low (67.0 ± 1.0 dBA), and FR-7800B high (77.4 ± 1.6 dBA). The Dunn's post-hoc multiple comparison test showed that the control BOB high, control human, FR-7800B human, Millennium BOB high, and Millennium human conditions were significantly higher than the FR-7800B low condition. In addition, the control BOB high and control human were significantly higher than the Millennium BOB low.

The one-way ANOVA on MRT scores showed that there was not a significant difference among the scores for the human speakers (89.2% ± 2.5%), BOB high (93.6% ± 5.0%), or BOB low (90.4% ± 2.4%).

ANOVA on ranks was performed to determine if there was a difference in PR based on the high versus low BOB trials. A significant difference was found between the BOB high trials (77.8% ± 15.2%) and the BOB low trials (48.5% ± 30.4%).

The two-way ANOVA used to determine if the PR differed based on the factors respirator (Millennium and FR-7800B) and speaker type (human and BOB high) showed a significant difference in main effects. There was not a significant interaction effect. The Holm–Sidak multiple comparison post-hoc test showed there was a significant difference between the FR-7800B (74.4 ± 15.5) and the Millennium (92.1 ± 9.7), and between human speakers (88.8 ± 14.3) and BOB high (77.7 ± 15.2).

5.3.2 Headform Pink Noise Trials

The frequency responses for the control, five respirator conditions, and chamber background noise (from the pilot trials) are shown for speaker pink noise of 70, 75, and 80 dBA in Figures 5.3 through 5.5, respectively.

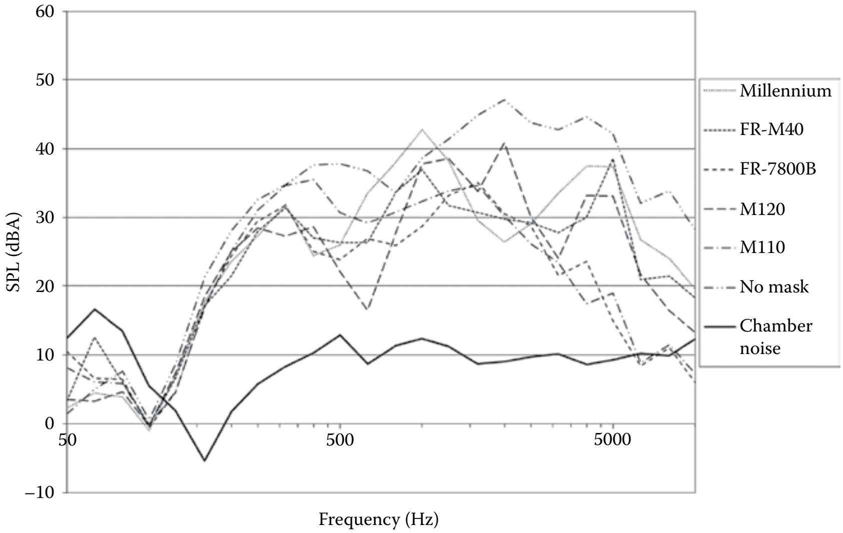

FIGURE 5.3
Frequency response of respirators with speaker pink noise of 70 dBA.

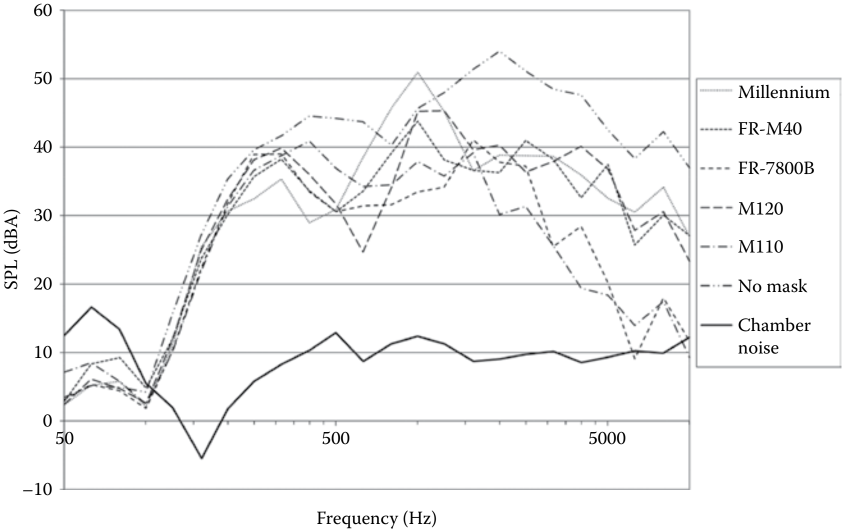

FIGURE 5.4
Frequency response of respirators with speaker pink noise of 75 dBA.

The TBP measured at the microphone for each of the respirators tested at each speech sound level is shown in Table 5.1. Values are mean plus or minus one standard deviation.

ANOVA on ranks was used because the equal variance test failed for the ANOVA. Statistically significant differences were found for the TBP among

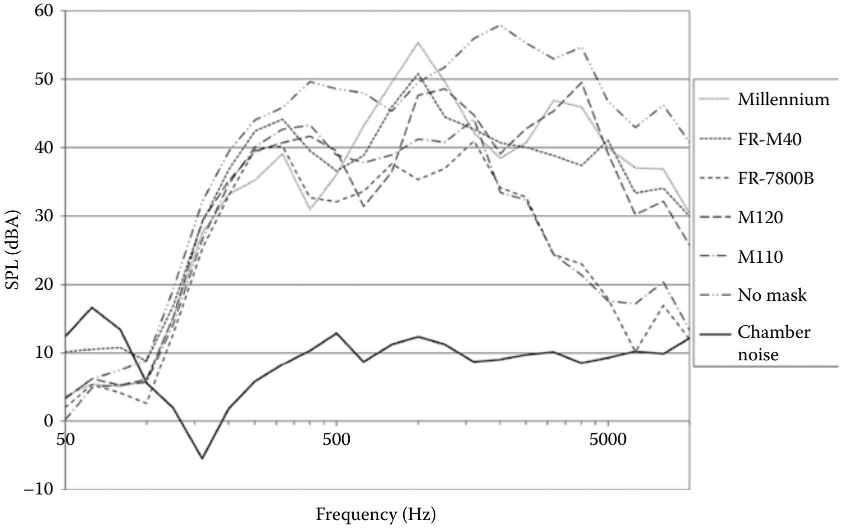

FIGURE 5.5
Frequency response of respirators with speaker pink noise of 80 dBA.

TABLE 5.1

TBP for the Respirators at Three Pink Noise Levels

Respirator	70 dBA	75 dBA	80 dBA
MSA Millenium	46.8 ± 0.2	53.6 ± 0.3	58.2 ± 0.4
3M FR-M40	43.5 ± 0.2	49.4 ± 0.2	53.6 ± 0.7
3M FR-7800B	40.3 ± 0.3	46.7 ± 0.3	47.2 ± 0.3
Scott M120	45.4 ± 0.2	51.3 ± 0.2	55.4 ± 0.2
Scott M110	42.6 ± 0.2	47.0 ± 0.3	50.6 ± 0.3
Control	53.1 ± 0.1	59.3 ± 0.2	63.7 ± 0.1

the respirators at each pink noise level. The significant differences were the same for each pink noise level. The control condition was significantly higher than the FR-7800B, M110, M40, and M120. The Millennium was significantly louder than the FR-7800B, the M110, and the M40. The M120 was significantly higher than the FR-7800B and the M110 while the M40 was higher than the FR-7800B.

Linear regression on the MRT and TBP data generated equations for 70, 75, and 80 dBA that were statistically significant ($P = 0.016$, $P = 0.028$, and $P = 0.007$, respectively). The equations were

$$\text{MRT} = 35.2 + (1.1{*}\text{TBP})\ (70\ \text{dBA})\ \text{Adjusted}\ R^2 = 0.75$$

$$\text{MRT} = 34.0 + (1.0{*}\text{TBP})\ (75\ \text{dBA})\ \text{Adjusted}\ R^2 = 0.68$$

$$\text{MRT} = 36.7 + (0.92{*}\text{TBP})\ (80\ \text{dBA})\ \text{Adjusted}\ R^2 = 0.84$$

5.4 Discussion

The speech signal transmitted by the BOB was impacted by which respirator was worn. The FR-7800B attenuated the sound transmitted more than the Millennium. This aligned with reports from volunteers in previous studies who indicated that it took more vocal effort to be heard wearing some of the respirators than others. The Millennium caused approximately a 4 dBA attenuation of the BOB high speech and 6.5 dBA of the BOB low speech. The FR-7800B decreased the BOB high speech signal by 6 dBA and low speech signal by 10 dBA. The Millennium had higher MRT scores than the FR-7800B during the study with the NIOSH format (Coyne and Barker, 2010, 2014) and the study with the experienced speaker (Coyne and Barker, 2015). One of the reasons for the difference in speech intelligibility performance is likely this difference in attenuation. These results also point to the impact of the large range of acceptable speaker sound levels permitted by the NIOSH MRT test standard. For example, if human subject speakers for a NIOSH trial spoke at the upper limit of 85 dBA for Millennium trials but spoke at the lower limit for the FR-7800B trials, a 13 dBA difference in transmitted sound levels could be approximately generated. A speech level of 85 dBA is twice as loud as speech at 75 dBA.

There was no significant difference among the MRT scores for the three control conditions. So, even though the BOB low trials had a speech level 6 dBA lower than the BOB high trials, the volunteers were able to understand the words spoken. However, when the respirator was donned on the BOB, the listeners only had a PR of 49% on the BOB low trials compared to the 78% on the high BOB speech levels. The signal-to-noise ratio (SNR) is an important factor for speech intelligibility. As the background noise level stayed the same, the SNR would have been higher for the BOB high trials compared to the BOB low trials and explains the increased MRT PR at the higher BOB speech levels. This is further indication of the impact of the large NIOSH permitted speech range on MRT performance.

The two-way ANOVA showed a significant difference between the FR-7800B and the Millennium. This was not surprising based on the results from the previous studies. What was unanticipated was the fact that the human speaker trials resulted in significantly higher PR (89%) than the BOB high (78%) trials. The variability in the headform trials (15%) was similar to that for the human speaker trials (14%). It was expected that the BOB trials would decrease the variability in PR versus the human speaker. Different word lists were used for each trial. The sound level varied throughout each recording, so it is possible that the recordings used impacted the results. Using the same word list for BOB and human speaker trials would have eliminated this source of error. However, the volunteers may have begun to memorize the word lists if they heard the same list with each of the three human speakers and with the BOB high and low trials for each respirator. Also, the BOB's head points slightly downward. While the mouth simulator was positioned to account for this, the respirator speech diaphragm may not have matched up properly. In addition, the BOB's head was higher than the human speaker's heads since the BOB is meant to be a standing mannequin and could not be lowered enough to match the seating position. Although the acoustic performance of the BOB was checked by the consulting company that designed it, it is possible that over time some changes in the calibration and performance occurred. It would be interesting to repeat the speaking headform trials with a head and torso simulator such as the K.E.M.A.R. HATS manikin (G.R.A.S., Denmark) which is designed specifically for intelligibility testing. Lastly, due to the large variability in PR, it would likely help to have a much larger pool of listeners.

Figures 5.3 through 5.5 show that the FR-7800B and Scott M110 experienced a drop off in sound level starting at 1600 Hz, regardless of the initial SPL. The SPL for those two masks drops into the range of the noise floor more quickly for the 70 dBA trials. For the 80 dBA initial sound level, the Scott M110 frequency response closely follows that of the FR-7800B up until 5000 Hz. The higher SPL at the higher frequencies may partially account for the higher MRT PR for the Scott M110 versus the FR-7800B (Coyne and Barker, 2010, 2014). The MSA Millennium, FR-M40, and Scott M120 show similar frequency responses, with the SPL drop off point occurring at a higher frequency than the Scott M110 and FR-7800B. Frequency response of a system impacts speech intelligibility (Jones, 2014). Telephone systems are band-limited to 2 KHz, making it hard to discriminate between consonants such as "d" and "t" (Jones, 2014). Thus, the higher SPL at higher frequencies that would include many consonants is likely partially responsible for the higher PR for the Millennium and FR-M40. The Scott M120 and M110 had similar MRT PR (84.8 and 85.9 dBA, respectively), but different frequency responses, so the frequency response does not entirely explain the PR. Palmiero et al. (2016) showed a similar drop off in their frequency curves for modified STI-PA run on various half-mask respirators. However, the decline began at approximately 500 Hz.

The ranking of respirators by TBP did not change based on the initial pink noise speaker level. The loudest to quietest respirators were the Millennium, the M120, the FR-M40, the M110, and the FR-7800B. It is interesting that ordering was not exactly the same as for the MRT PR. The highest to lowest MRT PR respirators were the Millennium, FR-M40, M120, M110, and FR-7800B. So, TBP alone does not account for the MRT PR and neither does the frequency response. In fact, the M110 and FR-7800 had similar frequency response and TBP, but the M110 scored a PR of 86% on the NIOSH MRT test while the 7800B scored a 78%. There was a significant relationship between the TBP and MRT PR for each of the three pink noise levels. However, only 68%–84% of the variability in MRT PR was explained by TBP as evidenced by the adjusted R^2 values. Thus, there is something beyond the frequency response of the respirator that impacts speech intelligibility. The MRT includes aspects of actual respirator usage that cannot be captured in an objective test like the STI-PA. In fact, tests like the MRT also include variabilities due to human perception and behavior (Voran, 2013).

Hollman et al. (2011) showed that the STI reference at 3 m with 60 dBA pink noise was only 0.52. According to Palmiero et al. (2016), this corresponds to 78%–87% of intelligible words (STI 0.45–0.6). So, 0.52 would be approximately 84% of intelligible words. However, the no mask condition for MRT with 60 dBA background pink noise and a person speaking at 75–85 dBA (measured ~30 cm in front of the mouth) is regularly above 90% (Coyne and Barker, 2010, 2014, 2015). Therefore, there appears to be a disconnect between the STI and the assessment of intelligible words that would be transmitted.

There are ways to improve the conduct of the MRT to decrease the subjective variability. Highly trained speakers can provide a small but significant increase in PR (Coyne and Barker, 2015). Specific protocols can be used to increase PR and decrease response time (Johnson et al., 2001). Some listeners have shown improvement in MRT scores after prior binaural exposure to room acoustics as they may undergo perceptual adaptions due to prior exposure (Brandewie and Zahorik, 2011).

There is debate in the respirator community regarding which type of test is the best way to assess speech intelligibility. The MRT uses human test subjects, increasing test cost, time and subjectivity as compared to the STI. The STI-PA could provide a faster, lower cost, repeatable measure of mask speech conveyance and intelligibility compared to the MRT. However, there are significant drawbacks to using the STI for respirator speech intelligibility. These include the lack of respiration, the fact that the respirator as donned on the speaking mannequin may not reflect how the respirator is worn (e.g., regulators may not be on or valves may not be in the correct state), and the "listener" is a microphone and thus does not replicate binaural hearing or the impact of a worn respirator on the sound transmission path to the ears. Respirators that use a speech horn may not perform well on the STI-PA because exhalation is necessary to open the exhalation valve. This lack of respiration deviates the speech transmission path from what it is during actual operational usage of the respirator.

Breathing can impact intelligibility due to sounds from inhalation and exhalation that may become amplified by a voice amplifier (Sell, 2011). Respirators with speech horns such as the Avon FM12 and the Avon C50 both rely on the exhaled air that occurs during speech to open the exhalation valve and allow sound to be emitted. Other respirators that couple speech transmission with the outlet valve may also be impacted. The STI does not include respiration, so respirators with a speech horn may receive lower scores due to the mechanics of the test rather than the speech intelligibility with the respirator.

5.5 Limitations of the Study

The speaking mannequin trials were conducted as part of a larger MRT test. The small number of subjects limits the application of the results. In addition, only two respirators were tested. The pink noise trials were not conducted at the highest speech level used for the NIOSH trials. Only five respirators were tested, and none of those had speech horns. It would be interesting to investigate what the sound levels projected through the speech horn are with the exhalation valve closed and with it cracked open to simulate exhalation. Unfortunately, the anechoic chamber and equipment were not available for further investigations. Finally, the sound recordings were not professionally recorded. The sound levels of all of the words may not have been constant.

5.6 Conclusions and Recommendations

The five respirators tested all impacted the frequency response of a transmitted pink noise signal. The TBP was related to the MRT performance of the respirator, but did not explain all the variability. Factors other than the speech signal such as valve noise, breathing noises, human perception, and room acoustic experience are all aspects of the MRT that are not captured by an objective test such as the STI-PA. The limited mannequin speaker trials conducted in this effort did not show an improvement in either MRT scores or score variability. However, there were limitations with the mannequin and a small number of volunteers. It is likely that using a calibrated mannequin with a professionally recorded MRT word list would decrease the variability in listener responses. For the no mask control condition, there were no differences in MRT PR whether the simulator or human speakers were used. Using an automated speaker would also eliminate speaker training, decreasing cost and the time to run the test. It would also ensure that the listeners heard each word list at the same sound level. This is important because this effort showed that scores when speech was at 85 dBA were significantly higher than when speech was at 75 dBA.

The NFPA data show that the STI-PA yield different impacts of distance and noise level depending on which facepiece is used. In addition, the STI-PA, frequency response, and TBP do not account for actual wear factors such as valves, noises, regulators, horns, or perception. Respirators may pass one test standard, but not the other indicating that neither method will inform the user as to which respirator will provide the greatest speech intelligibility in the field. Something missing from the test methodology discussion is the relationship between STI-PA scores and MRT PR on operational performance. While some limited work has been done in this area, a full understanding of the relationship between these test scores and operational performance has not been realized. That is, are health care workers, law enforcement officers, and fire fighters able to communicate adequately when they are wearing certified APRs to perform their operations effectively and ensure that life threatening mistakes are avoided? This linkage between laboratory test results and operational effectiveness is crucial regardless of which test methodology is utilized.

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Section II

Program Management

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6

Respiratory Protection Medical Clearance

Steven M. Hetrick

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6.1 Introduction

The Occupational Safety and Health Administration estimates there are approximately five million workers who are required to wear respirators at the time of this writing (OSHA 2016). The cost of providing respiratory protection to manufacturing, construction, maintenance, service, health care, agricultural, and commercial workers is a large and expensive challenge for employers. This text endeavors to delineate and discuss the multitude of scientific and administrative subjects involved in the provision of appropriate respiratory protection to workers. This particular chapter focuses on a very critical component in affording that respiratory protection—the human health element. Airborne hazards in the workplace have the potential to cause burns, tissue damage, cancer, lung disease, central nervous system suppression, systemic disease, or even death. The stakes in providing effective protection to our workers are obvious. The raison d'etre of medical clearance for respirator use is to determine whether a given worker, with a defined level of health or impairment, can tolerate wearing a respirator and still capably and safely carry out his or her assigned task. Over the following pages, discussion will encompass suggested content of a medical evaluation, medical conditions that may increase risk or interfere with respirator wear, special medical considerations for various types of respirators, and the use of a questionnaire.

6.2 The Respirator

The respirator is a protective device that prevents inhalation of hazardous airborne substances posed by the workplace. Specific types of respirators differ in the manner in which they protect the worker, the way that they fit, their size, and weight. Respirators afford health protection by eliminating the hazardous material from the air that is delivered to the worker, or by providing a safe supply of respirable air to the worker in cases of oxygen deficient atmospheres (via airline or tank). The airborne hazard could be in the form of a vapor, particulate, mist, fume, aerosol, or dust and may be removed by the respirator by means of a filter, sorbent, catalyst, or combination of these mechanisms. The spectrum of the hazard could range from that of a mildly irritating dust to a vapor immediately harmful or fatal even at low concentration. The physical and chemical properties of the hazard are an important parameter driving appropriate respirator selection. Anticipated concentrations of the hazard and the degree of danger to life and health in the workplace atmosphere must also contribute to the selection process. The respirator can also provide protection against contact exposure to hazardous agents for the mucus membranes of the eyes, nose, and throat. The respirator may serve as part of a protective ensemble which could include a hood, a protective suit, gloves, and boots, thus helping to provide whole body protection from the hazard. Despite its formidable technology, the respirator is a device that constitutes only a part of the scientific, medical, administrative, and supervisory array of initiatives leading to the successful protection of the worker.

6.3 Respiratory Protection Program

An amalgamation of science, administrative structure, and interdisciplinary cooperation aimed toward protecting workers from airborne hazards is an absolute requirement for an effective respiratory protection program. Coordinated efforts from governmental agencies, professional organizations, industrial hygienists, research workers, and respirator manufacturers have collectively provided a comprehensive approach to solving problems with respiratory protection. Those efforts have led to the development of technologies, best practice guidelines, standards, and regulations that ultimately provide effective protection for individuals in the workplace (Metzler et al. 2016). Occupational health professionals surmise that a successful respiratory protection program requires effective coordination between the medical professional, industrial hygienist, safety officer, employer, and worker (Szeinuk et al. 2000). Management is also acknowledged as having a key role in ensuring success of the overall program by its recognition of the need for respiratory protection and its provision of technically effective and ergonomically suitable solutions for the worker (Graveling et al. 2011).

A central tenet in the field of occupational medicine is the hierarchy of controls when attempting to protect workers from any hazard—be it physical, chemical, or biological. Whenever possible, a worker should be protected against an airborne hazard by engineering controls—that is, finding a solution that physically separates the worker from the hazard (Figure 6.1). If strategies such as elimination, substitution, or creating an engineered barrier between the hazard and the worker are insufficient or infeasible, administrative controls should be attempted, limiting access, time of exposure, etc. through rules and restrictions. As a last resort, the worker will need to be protected with personal protective equipment, which includes the use of a respirator. Although respirators are capable of providing excellent protection to workers from airborne hazards, as with any piece of personal protection

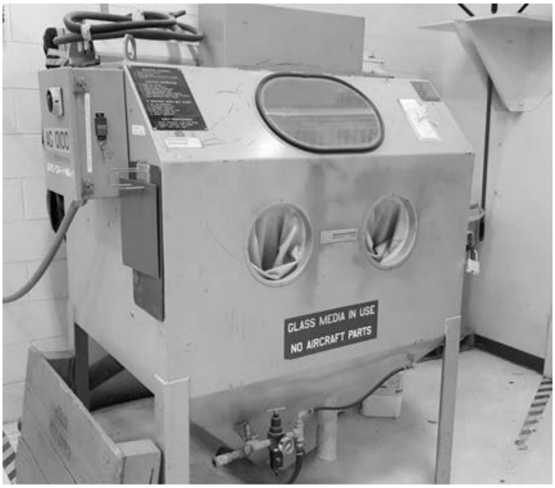

FIGURE 6.1
This is example of an engineering control to keep a worker safe from an airborne hazard. A glove box is used to remove paint and primer from parts by media blasting. The design eliminates airborne hazards generated by the blasting process by completely separating the hazard (in this case, hexavalent chromate) from the worker. This method allows the worker to operate in a "shirt sleeve" environment, eliminating the stressors associated with protective clothing and respirator wear.

equipment, their effectiveness relies on human behavior, proper fit, proper technique, and consistency of use (compliance).

6.4 Physiologic Effects of Respirators

Respirators are probably the least effective means of protection against airborne hazards, and are also very costly for employers (Cashman and Muray 1995, Kellerman et al. 1998). After selecting a respirator appropriate for the hazard in the workplace, the respiratory protection team must determine if the worker can tolerate wearing the device (Figure 6.2).

Even with the healthiest and fittest worker, a respirator has the potential to, at a minimum, become uncomfortable with prolonged use and in some cases cause physiological effects to the wearer. Respirators can impact both breathing and respiration as will be explained in the following sections. The cardiovascular system can be taxed by the increased work load inherent to respirator wear. These devices add to the thermal load placed upon the worker which most certainly impacts comfort and, ultimately, tolerance. Because they are often worn while doing cooperative

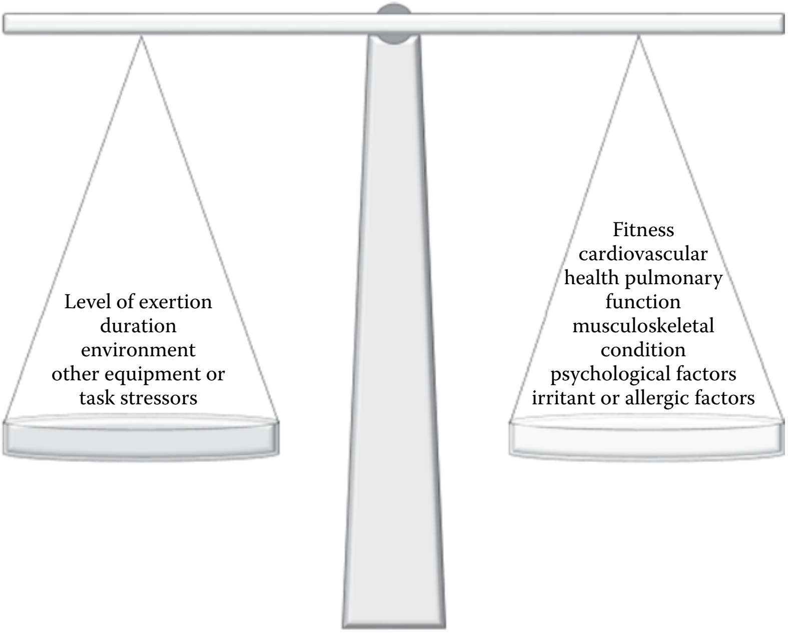
Level of exertion
duration
environment
other equipment or
task stressors
Fitness
cardiovascular
health pulmonary
function
musculoskeletal
condition
psychological factors
irritant or allergic factors

FIGURE 6.2
The balance depicted illustrates the need to assess between demands of the work and implications for the worker's health and ability to tolerate a specific type of respirator.

work, respirators' impact on communication cannot be understated. In the author's experience, workers and supervisors are particularly cognizant of the potential detriment to clear and immediate communication in safety-sensitive activities.

Although respirator use clearly interferes with a variety of commonplace activities, it is important to assess the impact on the individual worker. For example, a worker cannot eat or easily drink while wearing a respirator, although some models do offer drinking tubes. For most workers, this is not an issue, since both activities may be pursued when the task is completed or a work break is taken. However, workers who must work in a hot environment and perhaps have a history of heat illness will be faced with the challenge of increased heat load and decreased water intake while needing to wear a respirator. A diabetic worker experiencing symptoms of hypoglycemia cannot easily ingest glucose-containing food if wearing a respirator without stopping work and breaking the respirator seal. Eating or drinking in a hazard-contaminated environment would pose additional concerns with the risk of ingestion of the hazard. When a worker acquires an upper respiratory infection, coughing and blowing the nose become problematic activities. Even the simple facial itch can become a challenge to the worker when wearing a respirator (Figure 6.3).

The negative effects of respirators become more pronounced as work intensity increases. Filtering face piece respirators pose the least significant effects to the worker. Powered air purifying respirators (PAPRs) tend to be more easily tolerated than full face non-powered (negative pressure)

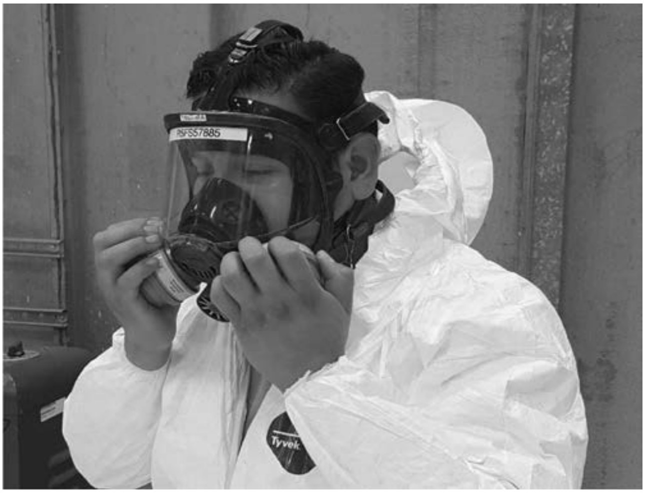

FIGURE 6.3
An aircraft maintenance worker performs a seal check on his tight fitting air purifying full face piece respirator. Filter canisters are specific to the workplace hazard. Visual limitations, thermal stress, impaired communication, and discomfort from pressure points are cited by users.

air purifying respirators. Physiologic impact is greatest with self-contained breathing apparatus (SCBA) while performing high intensity work. If worn for prolonged periods of time, respirators may reduce work efficiency (Johnson 2016). In addition, perception of comfort and tolerance to a particular respirator vary considerable from worker to worker. Workers may report difficulty or an unwillingness to deal with pressure or breathing resistance while wearing a respirator. Individuals may complain of feeling uncomfortably warm, note "hot spots" or soreness at the site of the respirator seal, or feel anxious with wearing the apparatus. Workers who require SCBA often need to wear heavy protective clothing. These same workers may be challenged with high metabolic workloads, amplifying the effects of SCBAs.

In a healthcare setting where workers require N95 wear, physiologic changes would be expected to be minimal since the worker is breathing through the entire area of the face piece. Discomfort is a common complaint with prolonged wear and is probably related to increased facial temperature. A study that looked at healthy pregnant healthcare workers using N95 respirators while exercising lightly, demonstrated reduced mean tidal volume and lowered minute ventilation among subjects (Tong et al. 2015). Oxygen consumption and expired CO_2 were also reduced. Prolonged use of N95 respirators has not been shown to have significant physiologic effects, but subjects did complain of perceived exertion and perceived dyspnea (Rebmann et al. 2013). The magnitude of discomfort has been shown to increase significantly with duration of wear (Shenal et al. 2012). Commonly used respirator models in health care settings were shown not likely to influence worker productivity (Shenal et al. 2012). Mean skin temperature under the respirator mask has been shown to increase by several degrees and probably contributes to wearer discomfort (Laird et al. 2002). Low flow ambient air cooling of the face under low work intensity and mild hyperthermia appears to decrease thermal strain and reduce respirator discomfort (Caretti and Barker 2014).

Wearing an air purifying respirator requires increased effort to open valves and draw air through filters. Increased inspiratory resistances (>0.39 kPa) have been shown to elicit perceived exertion and breathing discomfort among workers (Caretti and Whitley 1998). Respirator wear has been shown to decrease pulmonary function measurements by approximately 10% from that of a control set (Wilson and Raven 1989). The increased work of breathing due to resistance against a negative pressure respirator may exacerbate dyspnea in a worker and decrease work tolerance in terms of duration or intensity. A study that analyzed performance with different respiratory resistances during hard work demonstrated that increased inspiratory resistance was associated with decreased performance (Caretti et al. 2006). Increased inspiratory and expiratory resistance and increased dead space (discussed below) have been shown to impact breathing patterns and carbon dioxide retention (Louhevaara 1984). Increased resistance can increase tidal volume, but decrease respiratory rate, minute volume, and alveolar ventilation (Hermansen et al. 1972, Deno et al. 1981, Harber et al.

1989). In exercising subjects at submaximal to maximal levels, peak oxygen uptake was increased with respirator wear (Wilson and Raven 1989).

The use of fire fighter protective gear with SCBA has been shown to significantly reduce maximal speed of exercise, increase heart rate, and decrease work performance (White and Hodous 1987, Serra et al. 1998). A decrease in maximal power output has been noted with fire fighter SCBA wear, thought to be due to the extra mass of the device as well as friction and bulk of the protective ensemble (Louhevaara et al. 1995). At low intensity activities, heart rate with SCBA rises slowly and remains slightly elevated. An SCBA poses a significant increase in breathing resistance, increased work of breathing, increased cardiac demand, and musculoskeletal stress to the worker. Research using echocardiography on subjects exercising with SCBA has shown both increased inspiratory and expiratory pressures. The increased intrathoracic pressure reduces left ventricular preload (Nelson et al. 2009). Despite this decrease in preload during moderate exercise, the stroke area did not appear to change, believed to be due to a similar decrease in the end-systolic cavity area (Mayne et al. 2009).

The physical design of any particular respirator has an inherent amount of "dead space"—air volume within the device that must be moved with ventilation but does not contribute to gas exchange (respiration). This volume must be added to the physiologic dead space already existing in a worker's mouth, trachea, and airways (typically about 150 mL). Respirators having the largest volume of dead space include full face piece, non-powered air purifying respirators, full face piece PAPRs, full face piece airline respirators, and SCBAs. A full face piece respirator could introduce over 800 mL of dead space to the worker. The last phase of exhaled breath is from the alveoli, and a portion of this air remains in the respirator. Thus, on subsequent inspiration, the proportion of oxygen is reduced and carbon dioxide is increased by including some rebreathed air. The effect of dead space can potentially impact the wearer's respiratory drive. Carbon dioxide (CO_2) concentration is monitored by central chemoreceptors in the brain's medulla and is more important for controlling respiration than oxygen (O_2) tension, which is monitored in the carotid sinuses. Workers being considered for respirator wear having certain neurologic afflictions such as Parkinson disease or multiple sclerosis could have an impaired ability to respond to increased carbon dioxide levels, and thus not respond to the dead space effect with increased respiratory drive (Aboussouan 2005). The residual exhaled air trapped inside the respirator also raises humidity, adding to discomfort.

Military gas masks are physiologically challenging because of increased resistance to inspiration and exhalation and the necessity to wear the mask with chemical protective jackets, trousers, boots, gloves, and hood. Heat casualties during military operations requiring the highest mission-oriented protection posture (MOPP 4) require diligent monitoring. Altered work/rest cycles are a necessary administrative control to mitigate the threat of heat casualties.

6.5 Questionnaire Use

The revised OSHA respiratory protection standard directs the employer to utilize a physician or other licensed health care professional to perform a medical evaluation of an employee's ability to work with a specific respirator. Such an evaluation begins with a self-administered questionnaire. The OSHA-provided questionnaire queries the worker on demographics, height, weight, and type of respirator required in Part A, section one (OSHA 1998a Appendix C). In section two of Part A, there are nine multipart questions intended for all respirator wearers that elicit information on tobacco use, medications, allergies, pulmonary and cardiovascular conditions, history of seizure disorder, diabetes, anxiety, claustrophobia, anosmia, and problems interfering with the past use of a respirator. Questions 1 through 9 apply to all wearers, and a question is included that asks if the worker would like to speak with a medical provider. In part B, questions 10 through 15 pertain to wearers of full face respirators and SCBA. These questions are designed to detect problems with the worker's vision, hearing, and musculoskeletal function. There are further questions on the specific hazards present in the workplace, the worker's occupational history, questions on the frequency and duration of respirator wear, and the intensity of work effort required while wearing the equipment. Environmental exacerbating factors such as heat, humidity, confined space, and lethality of hazards are further delineated. Equivalent questionnaires are permissible, provided they obtain the same information as the OSHA medical questionnaire. As with any questionnaire, the questions included affect the screening instrument's sensitivity and specificity.

Sensitivity defines the proportion of "positives" that are correctly identified—meaning the percentage of sick or impaired workers who are correctly identified as having health issues with respirator use. Conversely, specificity is the proportion of "negatives" that are correctly identified—meaning the percentage of healthy workers who are correctly identified as not having health issues with respirator use. The clinical utility of a questionnaire is impacted by its sensitivity and specificity. A very sensitive questionnaire will detect all workers who may have health or physical issues impacted by respirator wear, but would generate a large number of false positive individuals. Conversely, a very specific questionnaire would be expected to miss some workers (false negatives) who may not be able to tolerate wearing a respirator. In a 1999 study by Pappas et al. (1999a) at a Department of Energy complex, the questionnaire employed demonstrated 100% sensitivity in identifying workers needing restrictions, but had a low specificity of only 19%. Lung disease, cardiovascular disease, and claustrophobia have been shown to be the most common reasons for work restrictions.

As with any patient questionnaire, once the form is completed by the worker, it contains confidential medical information on a "patient" and becomes a privacy protected document falling under the Health Insurance

Portability and Accountability Act (HIPAA) Privacy Rule. As such, patient responses must be safeguarded from being viewed by supervisors, coworkers, or managers and remain within medical channels. The OSHA questionnaire addresses patient privacy within its directions to the worker. OSHA also requires employers to provide employees with instructions on how to appropriately deliver or send the completed questionnaire to the medical reviewer (e.g., stamped, pre-addressed envelope).

In most cases, after review of the questionnaire, no further evaluation is required to clear an individual for respirator wear. The majority of workers can be certified for respirator fit testing and wear on the basis of questionnaire responses alone. A disposition section of the questionnaire that is free of HIPAA sensitive medical information is signed by the physician or other licensed healthcare professional indicating the worker is cleared to move on to respirator fit testing. The completed questionnaire can be stored in hard copy or electronically in the worker's medical record. Employers must provide follow-up examinations for employees who give positive answers to any questions numbered one through eight. As with any medical examination, the physician or licensed health care provider may include physical examination, laboratory testing, diagnostic testing, or specialty consultation as deemed necessary. In some cases, all that may be required is a phone call to the worker from the provider to clarify an issue from the questionnaire (OSHA 2011).

6.6 Specific Considerations: Pulmonary Disease

Obviously, any worker who has health issues or an impairment involving the lungs needs further medical delineation before he or she can be cleared to wear a respirator. The worker may have decreased pulmonary reserve as a result of disease or impairment and could lead to shortness of breath during exertion. If the condition leads to inadequate oxygenation, both physical and cognitive performance could be compromised. If the worker has a frequent cough, produces significant sputum, or needs to use an inhaler, the worker may resort to breaking the respirator seal in a dangerous environment.

A worker's pulmonary function is normally assessed first by taking a history, inquiring about symptoms such as dyspnea or exertional discomfort. A focused physical examination of the chest, listening for air movement, rales, rhonchi, or wheezing may be helpful, along with office spirometry. Spirometry provides a means of measuring the volume of air exhaled and how quickly it is exhaled. A thorough discussion of spirometry is beyond the scope of this chapter, and the reader is directed to texts on the subject for further depth. A 2011 update of the American College of Occupational and Environmental Medicine (ACOEM) guidance statement on spirometry in the occupational health setting provides a helpful framework on the subject (Townsend et al. 2011).

This discussion assumes that the spirometry testing employed meets American Thoracic Society (ATS) and European Respiratory Society criteria for validity. It is also assumed that at least three acceptable curves are obtained, repeatability is within 0.15 L and the largest forced vital capacity (FVC) and forced expiratory volume over one second (FEV1) are used, even if taken from different curves (Townsend et al. 2011). The first and most obvious goal of spirometry is to evaluate the worker's pulmonary function as either normal or abnormal. Based on specific measurements, if abnormal, the worker's pulmonary function can be further assessed for the presence of obstruction or restriction.

Reference values provide the predicted mean value and the lower limits of the range for individuals' specific demographics. The lower limits of normal (LLN) equal the fifth percentile of the reference range utilized. They define the point at which 5% of non-exposed, asymptomatic workers would be expected to fall and define abnormality in spirometry. The ATS, ACOEM, and the American Medical Association (AMA) Guides to Evaluation of Permanent Impairment (6th Edition) recommend use of the 3rd National Health and Nutrition Examination Survey (NHANES III). Although commonly assumed to be a standard, use of 80% predicted value or an FEV1/FVC ratio of less than 70% is not recommended. LLN decline with age and can avoid including false positives among older workers and false negatives among young workers (Hansen and Wasserman 2007).

Two characteristics of abnormal lung function can provide an initial indication of what may be the etiology of lung dysfunction. Obstructive lung disease, such as asthma, chronic bronchitis, bronchiectasis, cystic fibrosis, or chronic obstructive pulmonary disease (which includes emphysema) results in damage to the lung tissue or narrowing of the airways, resulting in a slowing of exhaled air. Individuals with obstructive lung disease have difficulty moving air on exhalation and may have a hard time breathing during activity and report shortness of breath. During spirometry, patients demonstrate a decreased volume of air that can be blown out in one second—the FEV1. If the FEV1/FVC ratio and FEV1 are less than the LLN, obstruction is present.

In contrast, restrictive lung diseases cause the lungs to become stiff, making them resistive to expansion and decreasing lung volumes. Individuals with restrictive lung disease have a difficult time fully expanding their lungs during inhalation, meaning they have a hard time filling their lungs. During spirometry, FVC is decreased to below the LLN and the FEV1/FVC ratio is correspondingly higher than the LLN, and restriction may be present. Causes of restriction could include autoimmune processes, sarcoidosis, or interstitial lung disease caused by inhaling asbestos, silica, coal dust, grain dust, or certain molds. Severe obesity or neuromuscular disease can interfere with chest wall movement, secondarily impacting expansion of the lungs. As restrictive impairment progresses, both FVC and FEV1 decrease.

If disease is suspected with the use of screening spirometry, further delineation with volume plethysmography and chest imaging may be indicated.

The ability of spirometry to identify restrictive disease is considered to be poor, particularly if the prevalence of the disease is low. DeMatteis et al. (2016) propose using FVC <70% predicted and FEV1/FVC >70% to optimize specificity and positive predictive value. Ultimately, a worker's clinical pulmonary function, gauged by parameters such as symptoms at rest, symptoms with exertion, and specific lung volumes, needs to be assessed against the impact of wearing a respirator. The exertional demands of the work requiring the respiratory protection and the type of respirator selected must be part of this consideration.

Pulmonary function testing is not indicated for all patients being placed on a respiratory protection program. Across the board spirometry has not been demonstrated to provide sensitive or specific indicators. It should be reserved for clinically indicated delineation. Spirometry may be useful in evaluating a worker's capability and safety in meeting the demands of the task. Spirometry is considered an adjunct only for respirator tolerance. It should be used in targeted screening for workers with positive responses involving respirator symptoms or known disease, and for workers with increased risk. When assessing a worker with pulmonary disease, the presence of dyspnea is typically more significant than specific spirometry results.

The physician needs to carefully assess any worker with pulmonary disease and characterize the worker's functional capacity and stability, and consider factors present in the workplace that could exacerbate the condition before clearing for respirator wear. A worker who has an allergy to a substance that commonly occurs in the workplace (e.g., isocyanates) cannot be protected by means of a respirator. A similar concern arises for workers with pneumoconiosis if that hazard is present in the work environment or for the asthmatic worker who is triggered by a substance present in the workplace. If the worker's pulmonary condition is deemed stable and functional capacity appears to be sufficient to meet job demands, the worker can probably be cleared to wear a respirator. If there is ambivalence, a work trial is warranted, looking for evidence of dyspnea, significant discomfort, hypoxia, or decreased work tolerance. Other pulmonary diseases or conditions that impact ventilation, respiration, or patient comfort need to be assessed on a case-by-case basis. Acute processes such as pneumonia, pneumothorax, and thoracic trauma would obviously require a delay in respirator clearance to afford appropriate time for convalescence and re-evaluation.

6.7 Specific Considerations: Cardiovascular Disease

Cardiovascular disease remains the number one cause of death in the United States. The leading cause of death in fire fighters is heart attack

(Smith et al. 2015). Any worker under consideration for respirator wear should be screened for cardiovascular disease due to its common occurrence and potentially grave health consequences. The probability of cardiovascular disease increases with age and in the presence of risk factors. If the worker does not have a primary care provider, there may be a paucity of medical history available and the practitioner may wish to obtain laboratory studies to better appreciate cardiovascular risk. Fasting lipid panel results along with current blood pressure readings, age, gender, race, history of smoking, diabetes status, and use of antihypertensive medication may be used to calculate an estimate of the worker's 10-year risk of stroke or heart attack (an on-line calculator is available from the American Heart Association/American College of Cardiology [Goff et al. 2013]). Such delineation may provide the medical practitioner with reassuring or worrying information on the worker's fitness to wear a respirator—either concluding the medical assessment or driving further evaluation. When considering medical clearance for respirator wear, a fire fighter who must climb structures, fight fires, or extricate victims wearing heavy turnout gear and SCBA in a hot environment experiences significant cardiovascular stress.

Cardiac arrhythmias or a low cardiac ejection fraction pose an increased health risk or limited functional reserve that could be exacerbated by respirator wear. The additional mass of respirator ensembles and friction of protective clothing tax the cardiovascular system and increase the energetic cost of doing a given unit of work. If risk of sudden incapacitation is substantial, respirator clearance must be deferred until a clearer clinical picture is delineated.

Current angina pectoris or heart failure, high grade atrioventricular blocks, ventricular arrhythmias or supraventricular arrhythmias with rapid ventricular response, prolonged QT syndrome, and hypertrophic cardiomyopathy would all signal the need to initially defer respirator clearance. Workers with atrial fibrillation should be assessed for risk of stroke. For workers with ischemic disease or heart failure, ascertaining their functional classification is essential before clearing them to wear a respirator. The New York Heart Association functional classification categorizes patients by the symptoms they experience with ordinary physical activity, less than ordinary activity, or rest. In addition, workers may be classified according to objective assessment (evidence of no, minimal, moderate, or severe cardiovascular disease) (AHA 2016). Using the classification scheme, a worker's tolerance for doing work at different intensities can be predicted and matched against current work demands.

Workers who have suffered a cardiovascular accident (CVA) or stroke will need to maximally recover before being considered for respirator wear. If neurological deficits are present, they must be assessed for any impact they may have on the safe use of a respirator. Stroke recurrence is a concern for these workers, especially early on. Blood pressure control is an important concern when evaluating the worker with a history of CVA.

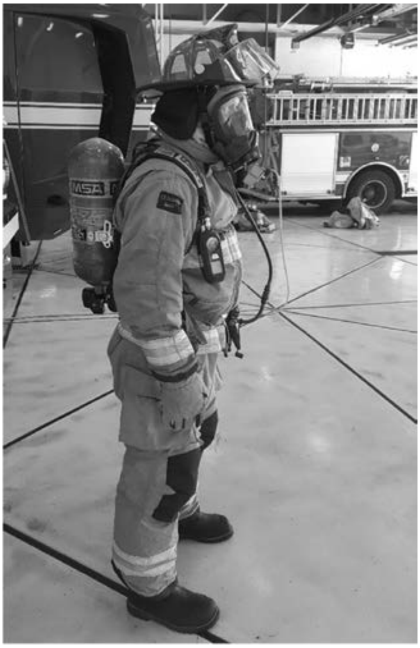

FIGURE 6.4
An example of a SCBA in a fire fighter, also wearing protective turnout gear. Fatigue, heat, and musculoskeletal stress are frequently cited by users. This heavy ensemble is used under highly demanding conditions in rescue operations or fire fighting.

6.8 Specific Considerations: Musculoskeletal Disease

It is not uncommon, especially in aging workforces to encounter workers who suffer from chronic low back pain, chronic neck pain, injured shoulders, or degenerative joint disease. Respirator use could negatively impact painful, stiff joints especially with SCBAs due to weight (Figure 6.4). Degenerative disc disease and arthritis of the neck may create difficulties for some workers wearing even lighter forms of respirators. Decreased range of motion due to joint pain or stiffness accentuates the effect of a full face respirator on peripheral vision. Airline respirators may create a trip hazard (see Figure 6.5) or become snagged in the workplace. If the respirator impacts equilibrium, a trial of wear may be indicated. Respirators add bulk to the head and can lead to impacts with nearby objects when in tight spaces. Postural instability, or sway, has been demonstrated in workers wearing respirators. This condition is seen to occur more quickly with increased workloads, possibly due to proprioceptive fatigue (Seliga et al. 1991). Protective clothing may be bulky and can further interfere with precision and ease of movement.

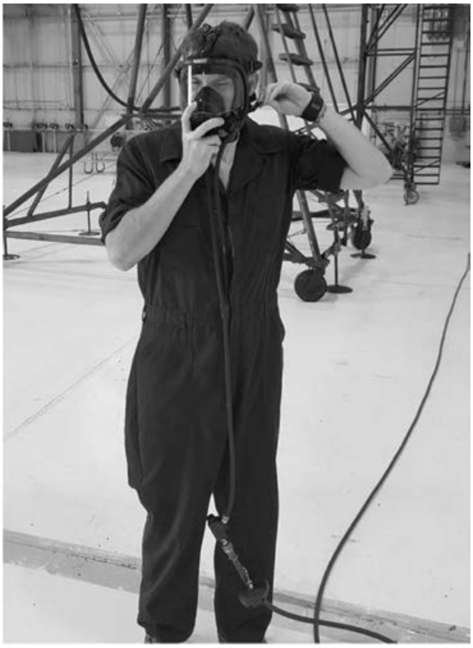

FIGURE 6.5
An aircraft fuel systems worker tests his full face piece airline respirator. Although comfortable to wear, the airline can pose a trip hazard or become snagged.

6.9 Specific Considerations: Sensory Impairment

The physical structure of the respirator (e.g., half face, full face, need for hood or helmet) has the potential to impair communications and awareness. Peripheral vision or other visual impairment is possible depending on the construct of the device. Use of respirators in cold environments can lead to face piece fogging, impeding vision. Corrective glasses must not be worn with full face respirators because the temple pieces break the respirator face piece seal, allowing contaminated workplace air to leak into the face piece. Institute of Occupational Safety and Health (NIOSH) requires manufacturers of approved full face piece respirators to provide spectacle kits which mount inside the mask for vision correction. Spectacle kits must be approved by NIOSH with the whole respirator assemblage and cannot be intermixed with other full face piece models. Respirator wearers may use contact lenses.

Hearing acuity may be impacted by respirator or protective ensemble wear, so workers with significant hearing loss must be assessed for functional impairment. A perforated tympanic membrane is usually not disqualifying for respirator wear, but needs to be weighed against the toxic properties of the airborne hazard. The ability to project speech and hence communicate with others is most certainly impaired. This can be a significant factor involving safety-sensitive activities. There are respirator designs that incorporate "voicemitters" or speech diaphragms to assist with this. Even radio communication is possible to incorporate within the design of a respirator. Employers should offer assistance to workers who suffer compromised vision or hearing acuity, impacted further by personal protective equipment use (Salazar et al. 1999).

For obvious reasons, a worker's sense of smell is significantly neutralized when a respirator is worn. However, a functional sense of smell is important for a number of reasons. Qualitative respirator fit relies on the subject being able to smell isoamyl acetate (banana oil), bitrex, or saccharin. Fear of failing the test or concern of the impact on employability could lead a subject to conceal smelling or tasting during the test. The quantitative test sidesteps this potential for concealment by directly measuring dust or other test substance in ambient air and comparing to mask air. Qualitative testing could be employed by using irritant smoke which alerts the subject even with anosmia. Another important role of smell is to detect respirator failure. Before the 1998 OSHA Respirator Standard had been enacted, workers with anosmia were not allowed to wear air purifying gas or vapor removing respirators because they could not detect when chemical breakthrough occurred.

6.10 Specific Considerations: Psychological Stressors

Workers with anxiety, those suffering panic attacks, or workers who indicate they suffer from claustrophobia need further assessment to determine the worker's tolerance of a respirator. Anxiety or panic could lead the worker to tear off the respirator and expose the worker to an airborne hazard. True claustrophobia may lead the worker to feel overwhelmed with dread or feel as though they are suffocating from the respirator. Effort should be made to allay worker anxiety when wearing equipment. Observation of use of the respirator at the worksite or in a simulated setting is indicated for these workers. Further assessment may include observing the worker wear the respirator while doing activity equal to the intensity anticipated in the job position. A combination of respirator wear and low-level activity does not appear to adversely alter cognitive performance or mood (as indicated by questionnaire) (Caretti 1999).

6.11 The Medical Evaluation

The medical evaluation is a required element of any written respiratory protection program. It is mandated by the Occupational Safety and Health

Administration 29 Code of Federal Regulations 1910.134 and assesses a worker's ability to use the selected respirator while performing required work activities and tasks. Additional statutory guidance concerning medical clearance for respirator wear is articulated by the American National Standards Institute (ANSI) and the Mine Safety and Health Administration (MSHA). An evaluation program needs to be overseen by a physician possessing knowledge of respirator design, potential effects rendered by respirators on the body, and clinical conditions that may be impacted by respirator wear. The medical evaluation must be given during the employee's normal work hours or at a convenient time and place for the worker. As with the questionnaire, the contents of the medical evaluation must remain confidential. The full cost of the medical evaluation must be covered by the employer. As the following pages will delineate, there is significant variance in exactly what is entailed in the process of "medical clearance." Published rates of respirator clearance are high—probably well above 90% (Pappas et al. 1999b). The evaluation must obviously precede the respirator fit test. It is only required once by most statutes (National Fire Protection Association (NFPA) stipulates annual reassessment), but if the worker, supervisor, or respiratory program administrator note evidence that respirator wear appears problematic, it may need to be repeated. At the time of subsequent annual respirator fit testing, questions are posed to the worker to reveal new medical conditions, changes in facial structure (affecting fit), or new job conditions that could affect respirator tolerance. Even if the respirator to be worn is for voluntary use, a medical evaluation may still be required, unless that voluntary use respirator is a filtering face piece respirator.

In a study contemporary with the writing of this chapter, an assessment of the standard of care for determining medical fitness to wear a respirator was conducted across occupational medicine providers in Michigan. Specific testing employed in medical clearances as well as the criteria utilized in determining fitness varied considerably among the practitioners queried (Desautels et al. 2016). This raises the question if there is insufficient guidance on the subject or if the variation among practitioners is an indicator of too little or too much testing among practitioners. Variations would be expected across work populations of differing risk (due to tasks, workforce demographics, and types of respirators and associated protective equipment required). A physician based in a medical center will probably do less diagnostic testing than the credentialed provider assigned to a refinery or chemical plant. In a study of private sector establishments, only 46% of employees were evaluated for medical fitness, however, this rate increased with establishment size (range 35%–95%). A large number of agricultural production-crops establishments are apparently not medically screened for respirator wear (Greskevitch et al. 2007, Syamial et al. 2007). The OSHA standard does not specify what particular testing a provider should accomplish, nor is there any criteria provided in the standard that specifically determines medical fitness for respirator wear.

It is difficult to provide an all-encompassing "go—no go" list of diagnoses or conditions that would prohibit a worker from wearing a respirator. The worker's health, level of fitness, chronicity of illness, functional reserve, experience, motivation, exertional level required by the work, and consequences of respirator failure all must be considered in the decision process. Most would agree that the disposition made by physicians or other licensed health care practitioners in determining respiratory clearance should be evidence based and not merely opinion driven. The disposition should be in keeping with community standards of medical care and follow applicable clinical guidelines or governing guidance. There has been an evolution over the past 30 years involving the medical basis for determining respirator clearance. This change is related to both developments within medical science, use environment, programmatic factors, and in respirator design (Harber et al. 1999).

Predicting respirator tolerance can be a difficult challenge for the clinician. Medical clearance for respirator use is a multidimensional assessment in that it needs to take into account factors about the airborne hazard, specific work task, selected respirator, and worker. The practitioner should also be familiar with the frequency and duration of required respirator use and in what sort of environmental conditions and under what level of physical demand and other protective equipment the respirator must be used. In medical jargon, the practitioner should rule in sufficient fitness to use respiratory protection and should rule out medical conditions that might compromise safety of wear.

The work load of a given task could run the gamut from sedentary to a highly demanding task. Activity or work intensity is usually quantified by the term metabolic equivalent (MET)—or metabolic equivalent for task. The MET is defined as a ratio of the metabolic rate of activity to that of rest. The rate of energy produced by the surface area of an average person seated at rest would be equal to 1 MET. Standing, doing light work might equal 2–2.5 METs, whereas brisk walking could equal 5 METs. Shoveling could exceed 8 METs. The higher the metabolic demand of the work, the more physiologically significant respirator wear becomes (Harvard SPH 2016). The type of respirator can place stress on the worker by increasing the work of breathing, thermal stress, and mechanical load on the body. The undesirable effects of respirators become accentuated during heavy physical work. Finally, the level of function of a given worker's respiratory, cardiovascular, musculoskeletal, integumentary, endocrine, and psychological capacity have to be taken into account. When such factors are identified as potentially significant, the breadth and depth of the medical evaluation are correspondingly expanded.

Some general principles that apply to respiratory program medical clearance warrant discussion. First is the tenet of the healthy worker effect—which has been discussed in the literature for several decades and illuminates the fact that the actively employed have had a more favorable mortality and morbidity risk than compared to the general population. This historically held tenet would predict that prospective entrants into a respiratory protection program are more likely to medically qualify by virtue of their current employment status. Unfortunately, the recent epidemic of obesity and obesity-related disease appears to be upending the healthy worker effect. Today's unhealthy worker can be even less healthy than individuals in the general population (Poston et al. 2011). Workers are progressively challenged with chronic illness such as obesity, hypertension, diabetes, obstructive sleep apnea, and coronary atherosclerotic disease. A related principle at play is that the physical demands of a given task (be that welding, fire fighter duty, painting, aircraft manufacturing, grinding, sanding, etc.) most often outweigh the demands posed by wearing a respirator. Said another way, if a worker is medically fit to perform the physical rigors of a job, he or she can probably tolerate wearing a respirator to do it.

An equally proven tenet in occupational medicine is that past worker performance portends favorably for future performance. Workers who have successfully worn respirators in the past will probably be able to do so in the future—barring significant interim health decrements. McLellan and Schusler (2000) recommend in their *Guide to Medical Evaluation for Respirator Use* that the medical professional avoid denying or restricting respirator use unless the employee wishes to avoid the attendant risks, placing more emphasis on reassessment after the worker has begun wearing the respirator. This approach has also been suggested by the ATS in its respiratory protection guidelines (Harber et al. 1996). It is important for every practitioner to recognize that restricting a worker from respirator wear could negatively impact employment.

There is no OSHA-mandated content of the medical clearance process aside from that of the questionnaire and review by a physician or licensed medical practitioner. When positive responses are elicited within the questionnaire, typically the medical provider charged with doing the respirator clearance meets with the worker to further delineate the responses given. An interview can do a great deal to clear up questions arising from the questionnaire. Significant "red flags" on a respirator questionnaire include significant respiratory disease, severe cardiac or cardiovascular disease, claustrophobia, or facial anomalies interfering with fit. These "red flags" need to be appropriately delineated in order to assess the condition for significant risk of substantial harm to the worker.

A worker who indicated has a history of chest pain on the questionnaire may provide an account of costochondritis, a distant history of pneumothorax, or gastro-esophageal reflux—so that the clinician can quickly dismiss significant concern for atherosclerotic disease, arrhythmia, or other cardiac issues. The medical practitioner may request medical documentation of past evaluations such as cardiac stress tests, perfusion studies, echocardiograms, or other subspecialty evaluations to ensure safety. A focused medical examination may also add information to the decision process.

Clinical tests that may be indicated by the patient's risk factors or responses might include chest plain film radiographs, resting electrocardiograms, and spirometry. Standard laboratory testing or diagnostic tests are NOT indicated for all workers being considered for respirator clearance. Several researchers have argued that physical examination and spirometry have been shown to add little to what can be garnered by questionnaire and history. Pappas et al. (1999b) determined a questionnaire was able to identify workers who need restrictions, but was not sensitive enough to pick up on those workers who had chronic disease.

An approach proposed by Balafsky et al. (2013) is to stratify screening protocols based on risk. This approach reserves medical resources for that stratum of worker with the highest risk. Low-risk workers may be screened with the use of a questionnaire only, whereas workers posed with higher physiologic loads due to the type of respirator and other personal protective equipment (PPE) required, combined with the task MET level, deserve greater scrutiny. This group also recommended that the periodicity of subsequent screening be linked to cardiovascular risk. Thus, a worker requiring SCBA or facing a heavy workload would be screened with questionnaire, exam, and spirometry as clinically indicated by responses and age. If risk factors are present, specific cardiac testing may have to follow to adequately assess tolerance.

Numerous review articles, position statements, and regulatory guidance have been written to address the question of efficacy of differing methods of respirator clearance. Most of these sources recommend screening with a questionnaire. Position statements and regulatory guidance also address the role of spirometry in predicting respiratory insufficiency or distress with respirator use. A large proportion of these sources recommend spirometry for older age workers and those faced with high demand work. Most position statements, regulatory guidance, and review articles recommend a tiered approach in formulating periodicity based on age and workload.

6.12 Medical Disposition

At the conclusion of the medical evaluation, the physician or other licensed health care practitioner must render a written disposition about whether or not the worker is able to use the designated respirator. Due to specific health conditions or impairments, any limitations on respirator use deemed necessary will also need to be conveyed in writing. An alternative form of respiratory protection may be recommended, provided the alternative (typically a PAPR in lieu of a negative pressure air purifying respirator) provides sufficient protection for the employee. The medical provider may also specify that an employee needs to return for follow-up medical evaluation based on clinical indication. As has been discussed, a fully accurate prediction of respirator tolerance is not always possible. Tolerance may depend more on the individual worker's perception of discomfort or psychological factors than physiologic impacts (Harber et al. 1996). Also, a worker's health would not be expected to remain static over time. Therefore, the certifying physician has a responsibility to ensure that the respiratory protection program is appropriately overseen and that there are administrative mechanisms in place to detect respirator wear problems that trigger additional evaluation. Although the physician's or other licensed health care provider's opinion is important, the final determination of clearance is left with the employer (OSHA 1998). Some professional associations indicate medical evaluation of older workers using a respirator or those using SCBA may benefit from recurring medical assessment.

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7

The Ergonomics of Respiratory Protection

Richard Graveling

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7.1 Introduction

What is ergonomics? To many, it is about how they sit at their desk or the layout of the controls in their car. The reality is very different and, although how people sit and work is important (as is designing their workplace to enable them to do that correctly), the science of ergonomics and human factors is much more far-reaching. For example, many major accidents attributed to "human error" have stemmed at least in part from designs that have failed to take ergonomics into account.

In Europe, the European Union (EU) Personal Protective Equipment (PPE) Use Directive (89/656/EEC, Council Directive 1989a) brought attention to the issue of the ergonomics of PPE, requiring that the PPE provided by employers must take account of ergonomic requirements, although it gave little information into what those requirements might be. Is it just about sizing? Does comfort come into account? What other requirements might be important?

Published the same year, the parallel PPE Manufacturers Directive (89/686/EEC, Council Directive 1989b) gave a little more insight. Applying to the manufacturers of PPE, rather than the employers who might buy PPE for their workers, it also specified requirements relating to ergonomics. Under the banner, "Ergonomics," it stated:

> PPE must be so designed and manufactured that in the foreseeable conditions of use for which it is intended the user can perform the risk-related activity normally whilst enjoying appropriate protection of the highest possible level.

A little further on, under the banner, "Maximum permissible user impediment," it further stated:

> Any impediment caused by PPE to movements to be made, postures to be adopted and sensory perception must be minimized; nor must PPE cause movements which endanger the user or other persons.

So, ergonomics is about more than comfort and fit—although these are important factors. Poorly designed ergonomics can get in the way of, restrict, or otherwise influence movement, or make it harder for the wearer to do their job in other ways (the user should be able to perform the [relevant] activity "normally"). If these restrictions lead to an employee not wearing his or her PPE, or failing to wear it correctly, then the result can be serious and possibly fatal.

On October 24, 1997, a young policewoman was on duty with the Armed Territorial Support Group of the Metropolitan Police in London. On that day, she and her colleagues raided a flat to arrest a man for breach of his bail conditions. After helping to ram the door of his flat to open it, the officer was stabbed through the chest with a knife by the occupant and died in hospital 2 h later. According to press reports afterward, she had removed her protective vest because it had been hampering her movements.

Unfortunately, the directives referred to above would not have helped her because the PPE Manufacturer's Directive does not apply to "PPE designed and manufactured specifically for use by the armed forces or in the maintenance of law and order." Nor does the PPE Use Directive apply to PPE "worn or used by the military, the police and other public order agencies," although not every EU member state applies this exclusion. It does seem a little strange that groups of people, who at times may be required to wear a considerable amount of PPE (and for whom, as related above, not wearing it can be fatal) should be excluded in this manner. However, whatever the legal position, it is clear that attention to the principles of minimizing "wearer impediment" may have been of benefit.

Although not wearing respiratory protective equipment (RPE) seldom (if ever) has quite such an immediate effect, it still has the potential to have fatal consequences. For example, a UK-based study (Health and Safety Executive 2016) estimated that in 2016, there were approximately 12,000 deaths each year in the United Kingdom due to occupational respiratory diseases resulting from exposures to chemicals, fibers (particularly asbestos), and dusts. Who knows in how many of these cases a failure to wear RPE was a contributory factor?

It is widely recognized, and must be acknowledged, that effective reduction of any risk at source is to be preferred, although efficient RPE would be preferable to undue reliance on ineffective controls. However, in many workplaces RPE is used, either as the only form of protection or as an additional defense to supplement other measures. As an example, research in the EU has established that 5.5 million workers are exposed to respiratory hazards in the workplace. Of these, approximately 50% wear RPE. However, it is also estimated that only 50% of these wear RPE that is correctly selected and fitted. It can be calculated from this that possibly only 25% of those at risk are adequately protected, which in turn suggests that a proportion of the remaining 75% could be at risk of ill health (not necessarily respiratory disease) from inhaling harmful substances.

This chapter briefly explores some of the issues relating to the ergonomics of RPE. Not all of them apply to all forms of RPE, and it must be said that some RPE manufacturers have made considerable progress in improving the ergonomics of their products. Nevertheless, it is important for the designers, manufacturers, purchasers, and users of RPE to be aware of these issues as the health or safety of users of that RPE might depend upon getting it right. Many of the issues are equally relevant to other forms of PPE.

As noted earlier, different people have differing perspectives or understanding of what constitutes "ergonomics." For some, in relation to RPE, it relates only to the physical aspects of the protective device. Others however, regard the organizational and behavioral factors, which some regard as "human factors," as part of the ergonomics domain. This chapter addresses both elements. Although it is important to get the physical attributes of the RPE right from an ergonomics perspective, it is equally important to address the attitudinal and behavioral aspects which will otherwise impact workers wearing PPE and wearing it correctly.

7.2 What are the Ergonomics and Human Factors Requirements for RPE?

To understand the ergonomics requirements for RPE, it is useful to start from the perspective of the would-be wearer or user. What are the factors that impact the wearer's willingness (or otherwise) to wear the RPE allotted to them—and to wear it correctly? This latter point is important; an employee paying lip service to the need to wear RPE by wearing it, but not wearing it correctly, might almost as well not be wearing it at all.

Graveling et al. (2009) included a review of the relevant published literature on this topic. They explored the evidence base for factors influencing the use (or nonuse) of RPE in the workplace. Although the study was framed against a perspective of RPE, the literature from which the evidence was drawn related to many other types of protective devices ranging from gloves and safety boots to fall-arrest harnesses.

The study identified a clear pattern in the factors influencing RPE usage, albeit one modified by the circumstances surrounding a particular industry or workplace. The key factors identified which influenced such usage amongst potential wearers were:

- Hazard awareness
- Risk perception
- Perceived effectiveness of protection
- Management/supervisory attitudes (including leading by example)
- Safety culture (e.g., attitudes of coworkers)
- Time and/or hassle involved with donning equipment

Clearly, none of these are specific to RPE, and the same factors can be applied to other forms of PPE.

7.3 Organizational Issues: Manage the Selection and Use of RPE

Graveling et al. (2011) summarized the important organizational (management) factors for an effective RPE program which incorporated many of these factors. Again, the recommendations can readily be applied to forms of PPE other than RPE. As the paper notes, much of the good practice advocated reflects legal duties, such as those within the member states of the EU, based on the EC Directive (89/656/EEC) and, in the United States, on the provisions of Occupational Safety and Health Administration Standards such as that relating to respiratory protection (Code of Federal Regulations 1910.134). These duties include:

- Managers at all levels need to recognize the need for RPE.
- All employees should accept their role in an effective program.
- Managers must ensure that appropriate RPE is selected which must be:
  - Technically appropriate
  - Comfortable to wear
  - Compatible with other PPE
  - Fits the individual
- Managers must ensure that sufficient RPE is provided.
- Managers must ensure that information and training needs are met.
- Managers must make suitable provision for cleaning, maintenance, and storage (as appropriate)

Although most of the individual items place particular emphasis on the role of managers, it is important not to overlook the importance of involving the workforce; and of the need for workers to play their part in selecting and wearing RPE.

Amongst the recommendations was the requirement for managers to ensure that appropriate RPE is selected. RPE must be technically appropriate and capable of providing the required level of protection. However, looking at this from another angle, it is almost as important to avoid overprotecting and to provide the right level of protection.

As noted above, ensuring the protection of the wearer from the risk the RPE is designed to protect against is paramount. In some instances, however, a desire to provide assurance of this has resulted in a "more is better" attitude, leading to concerns of overprotection. For example, although it is clearly important for firefighters to be given an adequate level of protection against the hazards they can face, a firefighter's protective clothing can be almost as good at keeping body heat in as preventing the heat from a fire from reaching the firefighter. A firefighter working hard needs to lose the heat their body is producing, or they will overheat without the help of the fire.

It is clearly important therefore to ensure that employees are provided with the right level of protection for the risk they face. In some cases, this might be a simple choice between a "bump cap" or the protection provided by a full safety helmet. In other instances, especially in the field of RPE, the choices can be more complex.

It is easy to think, "the bigger the better," and, for employers, providing a single (high) level of protection for all employees makes it easier for them to manage its use, as they do not then have to check that their employees are using the right level of protection for the job in hand. However, this can lead to problems and, in some cases, reduce the acceptability and wearability of the RPE. For example, types of hearing protection that provide the higher levels of protection tend to be bulkier and heavier, and the higher level of protection increases any sense of isolation. Studies have shown that these physical factors are more likely to discourage employees from wearing the hearing defenders. Although the differences between models of RPE providing different levels of protection are not so marked, there is still a tendency for those providing higher levels of protection to be bigger and/or bulkier and possibly with a higher respiratory resistance.

7.4 Human Factors Issues

There are three initial key human factors: hazard awareness, risk perception, and the perceived effectiveness of the protection provided. The individual who sees himself as somehow immune from falling off tall structures will be reluctant to wear a fall-arrest harness. Some workers will take the risk of not wearing a fall-arrest harness if it is going to take too long to fetch it and put it on before doing a quick job. Similarly, in the case of many respiratory hazards, the lack of any immediately apparent effect and the long latency before disease symptoms emerge can mean that the risks to health are less appreciated.

One such example is that of asbestos. As with smoking (my granny smoked 40 a day and lived until she was 90), not everybody working with hazardous substances like asbestos recognizes them as such (and, as with smoking, many asbestos workers know someone who lived to a ripe old age). As part of the Graveling et al. research into the factors influencing the use of RPE, informal interviews were conducted with a number of staff involved in providing asbestos-related services. Despite the well-established risks from asbestos exposure, many of the comments reflected poor attitudes to RPE use amongst those working in asbestos removal, with RPE not being worn correctly or being temporarily removed within enclosures. In many instances, this was seen to reflect general attitudes to the risk, together with a relative absence of management influence.

In another (earlier) unpublished study in the UK coal industry, some initial attempts to introduce the newly developed disposable RPE met with some resistance amongst some of the miners because they were accustomed to wearing heavy, rubber half masks and did not believe at first that such an apparently flimsy device could provide them with the same level of protection. The education of workers to understand the hazards and risks they are exposed to, especially ones which cannot be seen or otherwise sensed, is a key part of any RPE program.

7.5 Ergonomics Issues

This first set of factors, which are largely attitudinal or behavioral, were found by the review to impact the willingness of the worker to wear the RPE in the first place. However, once worn, a second series of factors, mainly more physical, and relating to comfort and disability issues, were found to impact the correctness of wearing the RPE or the willingness of the wearer to continue to wear the equipment:

- Lack of instruction and training
- The load (e.g., respiratory resistance) imposed by the device
- Discomfort (e.g., pressure and/or chafing)
- Thermal discomfort
- Impaired communication
- Other interactions/interference with work activities

Each of these are relevant to at least some forms of RPE, although similar principles can usually be applied to many other forms of PPE—again as reflected in many of the studies they were derived from.

7.5.1 RPE Should Not Get in the Way of the Job

This consideration can include physical obstruction (wearing bulky RPE or an industrial safety helmet or in a tight place), or the effects might be more subtle. As in the story of the police officer in the introduction to this chapter, the effects can be serious and potentially fatal.

By placing a barrier between the wearer's mouth and the outside world, RPE can have a negative impact on speech communication. Although not necessarily a large effect, it can be significant enough of an issue in noisy environments. If two employees need to talk about their job, what do they do? Turn the noise source off? Move to a quieter place? Shout? Or remove their respiratory protection? Howie et al. (1987) conducted a study of the UK coal-mining industry in which some miners indicated they would raise the visor of their powered helmet respirators when they needed to communicate with their colleagues.

It is interesting to note that similar problems can be encountered with hearing protection. As well as reducing sound levels, many forms of hearing protection distort the sound which does get through. They tend to remove the higher frequencies which are often important in understanding speech and allow more of the masking lower frequencies to pass through. If communication is an important part of the job, then careful selection of suitable hearing protection can make a big difference since types of hearing protection designed to facilitate communication (or at least to minimize any adverse effects) are commercially available.

Consider other examples of PPE which might be removed if it interferes with task execution: protective helmets removed in tight spaces, protective gloves removed to enhance dexterity, and visors or glasses removed because of poor visibility. In each case, the workers involved faced a dilemma: wear the PPE—or do the job—and chose to do their job.

7.5.2 RPE Must Be Comfortable to Wear

One way of maximizing comfort is to ensure a good fit. This is particularly important for RPE where having the right size and shape, correctly fitting the wearer, is critical. Take a look round at your workforce. Do you have men and women? What about different ethnic groups? We do not expect them all to wear the same sizes of clothes, so why do we think that we can buy one model of RPE and expect it to suit everybody? Studies have shown that most of the leakage which occurs with RPE in use is around the outside, not through the filter. Whatever its level of performance on a test dummy or a carefully selected test subject, if a mask does not fit the intended individual properly it will not protect him or her.

Although the effects are perhaps not quite so dramatic, other forms of PPE, such as safety footwear or hearing protection, differ in shape as well as size. Getting the right fit can make it easier to ensure that your workforce wear their PPE whenever it is needed. Would you like to be forced to wear uncomfortable shoes all day? If it is not comfortable when worn correctly, then either the employee will avoid wearing it whenever possible or he/she will not wear it correctly in order to ease discomfort.

Physical discomfort is only one element. Thermal discomfort is often raised as a barrier to wearing RPE and, especially in hotter climates, the thermal load created by wearing a safety helmet can lead to it being removed. Reference was made earlier to the risk of heat stress from "overprotecting" firefighters. The impairment of heat loss by clothing, especially non-vapor-permeable chemical protective clothing can generate a significant risk of heat stress, even in what might be regarded as moderate ambient temperatures.

7.5.3 PPE Must Work Together

Workers often have to wear other forms of PPE as well as RPE. Amongst the employers' obligations laid down by the EU PPE Use Directive was the instruction that,

> Where the presence of more than one risk makes it necessary for a worker to wear simultaneously more than one item of PPE, such equipment must be compatible and continue to be effective against the risk or risks in question.

Safety glasses misting up when worn with RPE is a commonly reported problem in the workplace, as is the discomfort caused by the arms of safety glasses being pushed uncomfortably against the side of the head by hearing protection. The side arms of those glasses may also impair the effectiveness of the hearing protection by breaking the seal between the cup and the side of the head. These are all examples of where different forms of PPE are not compatible with each other and impair PPE performance, cause the wearer discomfort, or make it harder for them to do their job. Again, the "fix" adopted is often to not wear one (or both) correctly—or to leave one off completely. In many such cases, alternative forms of protection are available, sometimes providing protection against more than one hazard that does not have such effects.

7.6 The Importance of Ergonomics on RPE

Clearly, any RPE provided must be up to the job, and RPE product standards such as those developed by standardization bodies such as the European

Committee for Standardisation (CEN) and the American National Standards Institute (ANSI) help to ensure their technical performance. Some product standards also address selected ergonomics issues (e.g., practical performance testing of RPE and dexterity testing of safety gloves). However, they do not cover every issue and cannot take into account the specific circumstances in which they will be used.

If RPE does not fit properly, gets in the way with work or with other PPE, is seen as too much hassle for the perceived risk, or even if it is too uncomfortable, then it will either not be worn at all or not worn correctly. When the injury occurs it is then easy to blame the individual for not wearing it—but who is really at fault? Looking at what employees are going to need to be able to do while wearing their RPE should be an essential part of the RPE selection process—and failing to do so can be a matter of life or death.

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Factors Influencing the Implementation of Respiratory Protective Equipment Programs in the Workplace

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8.1 Introduction

This report sets out the findings from a qualitative study in the United Kingdom examining respiratory protective equipment (RPE) programs across industry. This study involved research with 24 organizations between November 2008 and August 2009. This first section sets out the background and aims of the project before giving an overview of the research methodology. The section ends by laying out the structure of the rest of the report.

8.1.1 Background

This research was commissioned by the Health and Safety Executive (HSE), an arm of the UK government, to assist in improving the control of respiratory risks across industry. The RPE project identified a need for research to understand the behavioral aspects associated with managers' selection and implementation of RPE programs. Also, previous HSE research and anecdotal evidence gathered by HSE inspectors indicated the following:

1. A high rate of UK employees potentially at risk of developing respiratory disease. The 2005 HSE FIT 3 workplace survey (Thompson and Wake 2007) estimated that 5.5 million UK employees in 220,000 workplaces were potentially at risk of developing respiratory disease and up to half of these workplaces may be using RPE to protect their workers.

2. A general lack of awareness and concern for respiratory risks amongst employees. For example, in one study 17 welders believed the risks involved to be less significant than that of burns/heat (Murphy et al. 2008). A general lack of awareness was also reported in another study involving poultry farm workers (Hopkinson and Cummings 2007).
3. Organizational-level RPE failings (e.g., incorrect respirators, lack of training for employees on correct use). A study carried out to develop baseline intelligence on exposure and the control of respirable crystalline silica (RCS) in key industry sectors found a general need to improve risk assessments for tasks that cause RCS exposure in line with the "COSHH" (Controls of Substances Hazardous to Health) regulations. More specifically, where RPE was relied upon as a form of exposure control, it required better organizational processes and procedures in place, namely, selection, training, cleaning, and maintenance of equipment (Easterbrook 2008). Similar findings were reported in the poultry farm study (i.e., a lack of provision, training, and enforcement of RPE use) and elsewhere (e.g., Howie et al. 1996).

A literature review carried out by the Institute of Occupational Medicine (Graveling et al. 2009) found that most studies on RPE/personal protective equipment (PPE) have focused on compliance behavior (relating to point one above). Attitudinal and behavioral studies on RPE were scarce in the literature; those carried out examined worker attitudes and behaviors behind the use and nonuse of PPE generally (relating to point two above). Even fewer studies have addressed RPE successes and failures at the organizational/managerial level (relating to point three above). Although worker attitudes and behaviors were investigated in this research, the primary focus concerned understanding the influences on managerial decision-making underpinning RPE programs. After all, very little is known about how managers select RPE controls, what information this is based on, whether any gaps or misunderstandings are inherent in their decision-making process, and what the enablers and barriers are to good RPE practice. Additional reasons for focusing the research at the managerial level include:

- *"There is a lack of studies measuring managers' subjective evaluations"* (Holmes et al. 1997), yet it is management who ultimately decide what RPE program to put in place.
- It is widely accepted that directors who set a good example in their attitudes and actions toward health and safety promote similar attitudes and behavior in their workforce (Shearn and Miller 2005).
- A number of research studies (Kelloway et al. 2006) have shown that when leaders actively promote safety, organizations have better

safety records and more positive safety outcomes. *"Leadership is crucial to safety results (as it) creates and maintains the culture that determines what will and will not work"* (Petersen 2004).

- DeJoy et al.'s (2000) research indicated the need for making safety equipment readily available and reducing job-related barriers to compliance, both of which inevitably fall to management.

8.1.2 Aims and Objectives

This exploratory study aimed to address three research questions:

1. What do current RPE selection and use practices look like across industry?
2. How does this compare with "good practice" needed for compliance with the law and for adequate protection from risks associated with inhalation exposure?
3. What factors influence the current practices for choice and implementation of RPE programs?

In order to address these research questions, five specific objectives were identified to guide the design and conduct of the research:

1. Describe approaches to the selection of RPE that prevail in industry
2. Identify the factors (attitudinal, behavioral, or other) influencing the processes of selection, use, storage, and maintenance of RPE
3. Describe the types and levels of training and information provided by employers to operatives, and reasons for chosen approaches
4. Describe how employers with effective (or "good enough") RPE programs achieve this level of performance
5. Identify enablers and barriers to good RPE practice

The outputs from this research will assist both industry and government (HSE) to design communication interventions for employers and, to a smaller extent, employees, and will inform inspector training and dutyholder engagement strategy.

8.2 Methodology

8.2.1 Overview of the Research Process

This section provides an overview of the research process in the form of a flow diagram (Figure 8.1).

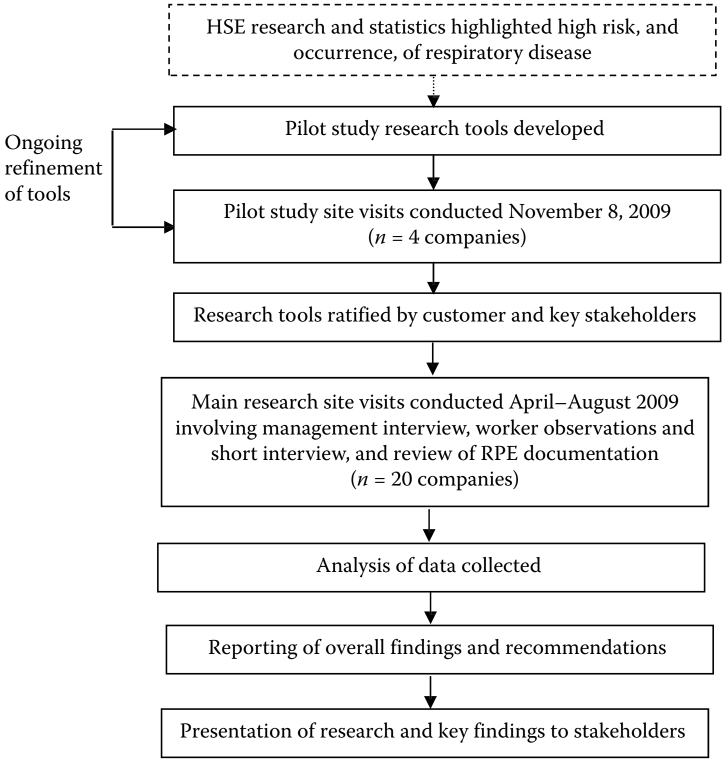
HSE research and statistics highlighted high risk, and occurrence, of respiratory disease
Ongoing refinement of tools
Pilot study research tools developed
Pilot study site visits conducted November 8, 2009 (*n* = 4 companies)
Research tools ratified by customer and key stakeholders
Main research site visits conducted April–August 2009 involving management interview, worker observations and short interview, and review of RPE documentation (*n* = 20 companies)
Analysis of data collected
Reporting of overall findings and recommendations
Presentation of research and key findings to stakeholders

FIGURE 8.1
Flow diagram of study methodology.

8.2.2 Research Design

The research was qualitative in design using a mixture of data collection methods during each site visit. In-depth interviews with managers were selected as the primary mode of data collection as the aims of the study required a detailed exploration of the drivers behind current RPE practice. Interviews lasted between 60 and 90 min and explored the decision making behind the selected RPE and other controls (e.g., local exhaust ventilation [LEV]); confidence in controls; limitations and concerns with the approach adopted; employee practices relating to the misuse of RPE; health monitoring/surveillance; instruction and training provided to workers as well as the storage and maintenance systems in place and reasons for adoption. The interviews were conducted using open, non-leading questions and answers were fully probed. All interviews were recorded once managers had provided written consent and recordings were later transcribed.

Observations of workers undertaking tasks requiring the use of RPE were also included (if practicable and safe) and short follow up interviews (5–20 min in duration) were carried out with workers to explore the reasons for the behavior observed. Observing RPE operatives in practice allowed the views of managers expressed during the interviews to be compared with actual practices on the ground. Observations generally lasted an hour, during which researchers completed an observational checklist. A review of available RPE documentation was also undertaken to provide an additional check on stated policies and procedures in the management interview with those actually in place. Comparison of the findings from the management and worker interviews, observations, and documentation review was considered sufficient for triangulation of the data.

8.2.3 Sampling and Recruitment

A team of experienced specialist occupational hygiene inspectors reviewed HSE's operational database and selected organizations and sites where work activities required the regular use of RPE. The sample included a mixture of high and low performing sites with regard to general RPE competence. Typical respiratory hazards that workers were exposed to included silica dust, general dust, fumes/vapors, solvents, chemicals, isocyanates, and asbestos. However, due to the nature of HSE's enforcement process and the limited size of the sectors involved, the database did not contain sufficient examples of all high-risk activities. A further group of premises representing foundries, brickworks, quarries, and welding/fabrication were selected by approaching HSE Sector groups. A soap works was also selected following this process.

The HSE customer sought permission from area inspectors to approach companies selected from the database. After obtaining approval, the HSE customer contacted individual companies by phone, briefly describing the research process before asking if the company would be willing to take part. The participant's contact details were then checked and a date and time for the site visit arranged. Once the companies had agreed to take part in the research, HSE researchers sent a confirmation letter to the company representative detailing further information about the research and the contact numbers of the research team should they have any questions prior to the visit. Forty managers and 63 workers participated in this research from a diverse range of industries (e.g., construction, brick making, quarries, foundries, manufacturing of composite components, metal fabrication, stone masonry, printing, and soap manufacturing).

Caution is advised when interpreting the results from this research; these should not be generalized across industry. Although the research meets a number of criteria relating to the reliability and validity of qualitative research (i.e., consistent and high quality fieldwork, systematic and comprehensive analysis, and interpretation that presents categories, themes, and explanations rather than simply individual accounts—see Ritchie and Lewis 2003), it falls down on the sampling strategy adopted. Robust, purposive sampling is necessary for the research to be generalizable. There is a strong possibility that the sample employed in this research was biased toward companies that were motivated (through HSE enforcement activity or close liaison with HSE through Industry Advisory Committees) to adhere to good practice in all aspects of their RPE program. These companies may have also received information and guidance through their HSE inspector about what they should and should not be doing to control respiratory risks within their organization. For this reason, findings from this research can only be considered as indicative of the factors and influences underpinning RPE programs within participating industries/sectors.

8.2.4 Data Analysis

8.2.4.1 Management Interviews

The analysis of the management interviews was separated into three stages. For the first stage, a spreadsheet was devised to capture separate information from the 20 participating companies for each interview question in turn. Researchers populated the spreadsheet with commentary and quotations taken directly from the transcripts. For the second stage, researchers analyzed the data identified at stage one for each of the 20 companies and refined it down, firstly into overarching themes and then down to elements (or sub-themes). For the final stage, researchers worked through the chartered data in detail to seek and explain emergent patterns and findings (e.g., company groups, company size, and sector differences).

8.2.4.2 Worker Interviews

A less stringent approach to data analysis was followed in the analysis of worker interviews than for management interviews in line with the research aims and objectives, which specify the need to focus on the organizational/managerial level (i.e., selection and RPE use practices, legal compliance, and influences on managerial decision-making surrounding choice and implementation of RPE programs). Analysis of the worker interviews involved the extraction of key themes that emerged from notes taken for each question asked during the interviews.

8.2.4.3 Post-Site Evaluation

Shortly after each site visit, two researchers (psychologist and PPE expert) rated each company on 48 defined aspects of RPE programs with a score ranging from 1 (exemplary good performance) to 5 (inadequate and poor performance). Scores were determined by extracting evidence for each of the 48 aspects from notes taken during interviews and observations, and making a judgment (i.e., "good"—a score of 1 or 2, "OK"—a score of 3, or "poor"—a score of 4 or 5) against set criteria for each component (e.g., supervision, training, etc.). Not all listed aspects applied to all types of RPE (e.g., aspects relating to filters were not relevant for breathing apparatus). As such, not all companies were rated on all 48 aspects. While not definitive or precise, these subjective ratings provided a broad indication of the observed competence and effectiveness of RPE programs in each company visited.

8.3 Company Groupings

Four categories of companies were identified from the research findings. These categories were “learners”, “developers”, “fortuitous”, and “proficient” (see Section 8.3.1 for full definitions). Companies were placed in a category on the basis of the subjective ratings that researchers assigned to each company after each site visit on up to 48 defined components of the RPE program (as detailed in Section 8.2.4.3). Each site was subjectively categorized as either “good” (a score of 1 or 2), “acceptable/OK” (a score of 3), or “poor” (a score of 4 or 5) on each component and on two overall dimensions. The overall dimensions were:

1. *General RPE competence* (i.e., an overall assessment of RPE competence of the organization)
2. *RPE control* (i.e., overall assessment of how well worker exposures were likely to be controlled by RPE under the regime prevailing at the time of observation)

Companies were categorized into two groups for each dimension, that is, “at least acceptable” (with a score of 1, 2 or 3) or “low” (with a score of 4 or 5). This produced four categories of companies, namely, (1) at least acceptable competence, low control; (2) low competence, at least acceptable control; (3) at least acceptable competence and control; and (4) low competence and control. This classification method was adopted to ensure that groupings were not based purely on what managers said during interviews, but actually reflected the reality of practice on the ground.

As shown in Figure 8.2, the better companies were categorized as “proficient” (managers were considered to have a good level of RPE competence and risks were under control). On the flip side, “learners” had recently begun their journey to better RPE performance and, at the time of the study, had some way to go to develop RPE competence and control of RPE risks.

The data collected during the management interviews was then explored to see whether any common features and characteristics were apparent among companies belonging to each of the four groups. These groupings were also used as an additional means for interrogating the data from both the management and worker interviews to seek and explain emergent patterns and

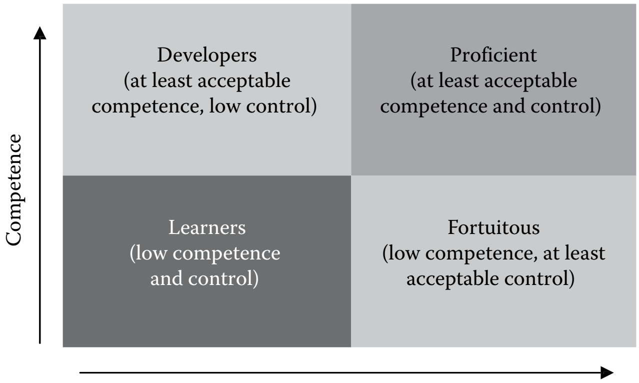
Developers
(at least acceptable
competence, low control)
Proficient
(at least acceptable
competence and control)
Competence
Learners
(low competence
and control)
Fortuitous
(low competence, at least
acceptable control)

FIGURE 8.2
Company groupings based on subjective ratings of RPE competence and control.

findings. Furthermore, this categorization was necessary for developing an understanding of how employers with effective RPE programs achieve this level of performance to answer one of the research objectives (Objective 5, see Section 8.1.2).

8.3.1 Features and Characteristics of Each Group

The defining features and key characteristics of each category/group are summarized in Figure 8.3. This is based both on notes taken by researchers during post-site evaluations and examining key RPE attitudes and behaviors described by managers during the interviews.

8.3.2 Company Groups by Sector and Size

Further comparisons were made between these groups by company size and sector. A few differences were found, namely:

- The small quarry had a better RPE program in place than the two medium-sized quarries and also had a more developed health and safety culture.
- Three of the four companies in metal fabrication were “proficient”. These were the medium to large-sized companies. The small company was categorized as a “developer”.
- Both foundries were in control of respiratory hazards, but one of these (the “fortuitous”) was fortunate to have workers with reasonable knowledge of how to use RPE obtained from previous jobs.
- Both companies that manufacture composite components had some way to go to establish competence in RPE performance and adequately control respiratory risks.

Proficient: These companies have a fit-for-purpose RPE programme. Management have at least an acceptable level of RPE competence and controls do appear to be working. Although marked by some degree of success in implementation of their programmes, a number of companies still have some way to go. **In only one case (tightly governed by asbestos regulations) was RPE performance considered to be "good practice"**. In most others improvements could be made on: storage, maintenance, training (e.g., providing refresher training), supervision/enforcement and RPE documentation. Specific characteristics include:

- Evidence of in-house health and safety knowledge and expertise.
- Senior management commitment/motivation to improve and recognition that their own actions influence their workers.
- Some provision of training (induction and fit testing as a minimum).
- Supervision/enforcement of RPE use in place.
- Close industry networks and a "social dialog agreement" with other companies.
- Proactive in searching for improvements using various external sources.
- General health and safety/housekeeping is a priority.
- Recognise the importance of having clear RPE procedures in place.
- Involve workers to accommodate preferences balanced against the RPE protection factor.
- Heavy focus on COSHH and risk assessments.
- Close monitoring of health/respiratory issues.
- Frequent verbal communications with workforce on RPE.
- Preference for engineering solutions and to use RPE as the last resort.
- Some evidence of a family business culture (moral driver to look out for colleagues health and safety).

Fortuitous: In these companies, workers are protected against the hazards that they are exposed to despite a significant RPE knowledge and skills gap amongst management accompanied by the absence of a structured RPE programme. Only two companies were included in this category. Similarities between them include:

- Significant gaps in RPE knowledge/awareness; management in need of RPE training.
- Assume that workers know how to protect themselves and rely on their RPE knowledge acquired in previous/other jobs.
- Rely on external information sources/RPE suppliers.
- Little communication/training on RPE.

Other features that emerged as being unique to each case were:

- **Case 1 (Foundry):** Limited management resource, but a sufficient level of commitment to health and safety; some degree of worker involvement through obtaining operative feedback on RPE; workers disciplined if they do not comply.
- **Case 2 (Construction company):** A complete disregard for what was actually occurring on the shop floor; consider that the company has done its job by providing adequate RPE; reluctant to implement occupational health arrangements for fear of subsequent claims from mature workers; no responsibility taken for sub-contractors.

FIGURE 8.3
Features and characteristics of each group.

Developers: These companies have RPE systems and procedures in place and are generally aware of what they need to do to protect their workforce against respiratory disease. Most fall down, however, on actual implementation of their programme. Specific characteristics include:

- Some evidence of in-house health and safety expertise.
- Keen to improve further, but want to be told what to do.
- Respond to others' (external) suggestions.
- Take an "educate workers" approach to enforcement rather than disciplinary approach.
- Want a simple life (e.g., no/little maintenance, simple stock control).
- Try to educate their workforce even though efforts are not wholly effective.
- Look to external people whom they trust and who they perceived to know the industry.
- Recognise that they still have some way to go on a journey to good RPE performance.
- Cost is an issue during times of low productivity.
- Heavily influenced by workers' wants and needs.
- Assume that workers know what to do, without adequate supervision/checks.
- Aware of having no formal maintenance programme in place.

Learners: These companies have recently started a journey better performance with regards to RPE. They are in the process of establishing a formal RPE programme and are continuing to develop their knowledge in the area. Specific characteristics include:

- Generally no in-house health and safety expertise.
- Overconfident that workers know the risks/how to protect themselves, and rely on this.
- Tendency to adopt an authoritarian style of management with little worker involvement or behaviour change attempts.
- Struggling in the recession.
- Senior managers happy to delegate health and safety to another manager.
- Opted for quick and cheap controls and assume that these are working until told otherwise.
- Unaware of the legal requirement to fit test and other necessary stages of the RPE process (e.g., proper storage, maintenance).
- A tendency for health and safety to be viewed as bureaucracy or a box ticking exercise.
- Heavy reliance on RPE manufacturers/suppliers for information.
- Respiratory disease is generally not considered a key risk unlike others (e.g., noise/HAVS).

FIGURE 8.3 (Continued)
Features and characteristics of each group.

8.4 Management Interview Results

This section presents the key themes that emerged across the interviews carried out with managers responsible for health and safety (including RPE) at the 20 sites visited. The findings address the following objectives for this research set out in Section 8.1.2:

- *Objective 1*: By outlining approaches to the selection and provision of RPE.
- *Objective 2*: By identifying factors influencing RPE selection, use, storage, and maintenance.

- *Objective 3*: By outlining the type and level of information provided by employers to RPE operatives and reasons for these.
- *Objective 4* (to some extent): By providing insights into how employers with good RPE programs achieve this level of performance ("proficient" vs. "learners", "developers", and "fortuitous" groups).

The key themes that emerged from the management interviews map onto critical stages of RPE programs, that is, (1) "knowledge, awareness and understanding" of respiratory risks followed by (2) "program selection", (3) "RPE use", (4) "training and advice", and finally, (5) "ongoing monitoring and maintenance". The findings have therefore been structured in this way. Any sector and company size (i.e., small/micro companies compared with medium/large) differences are highlighted under the relevant themes. Any differences between groups relating to each theme ("learners", "developers", "fortuitous" vs. "proficient") are also shown. Quotations to annotate the comments made by managers have been included and key findings for each theme are also shown.

8.4.1 Knowledge, Awareness, and Understanding of Risks

This section details the themes that emerged through the analysis of managers' responses to questions surrounding risk awareness, general knowledge, and understanding of RPE. Although not explicitly stated in the research objectives, this was included in data collection and analysis as it represents a significant prerequisite to RPE programs. Managers need to have an accurate understanding of their workplace hazards and potential consequences of not sufficiently protecting workers against these hazards to be motivated to act in the first place (Rogers 1983, Leventhal et al. 1984). No differences in management knowledge, awareness, and understanding of risks were found across company size and few sector differences were discovered.

Key findings include:

- Managers' risk perception was generally better than their RPE knowledge; they often thought they knew more about RPE than they actually did.
- Silica dust was the main primary risk cited. In some cases non-respiratory risks were considered primary (e.g., noise, manual handling).
- Respiratory risks were not a top priority in the foundries.
- Some managers did not equate nuisance dust with toxicity when it may have been (e.g., when silica dust was present).
- RPE knowledge stemmed from various sources: personal use, information share with other companies, external contacts (consultants and suppliers), publications and training, industry, and HSE events, guidance, and website.

- Key knowledge gaps were: the need for fit testing and being clean-shaven, proper storage and maintenance and awareness of RPE manufacturing developments.

8.4.1.1 Understanding of Risks

The overall opinion of managers across sites was that they had a good understanding of the respiratory risks inherent in their workplace. On occasions this stemmed from their own experience having worked their way up from the shop floor themselves. They felt that they had developed an appropriate approach tailored to the level of risk, driven by the need to reduce exposure levels in line with legislative requirements. On the whole, managers believed in the safe and proper use of RPE, including foundry managers even though respiratory disease was not considered a top priority for them.

> I've been in the industry for…36 years, so I know all… the dangers involved with the isocyanates…I've been using it for nearly 40 years so I know all the risks involved with sensitisation, respiratory problems and everything else.

When asked about their workers' understanding of respiratory risks, the majority felt that they were aware of the risks either because they had been in the industry for years or had previously/were currently engaged in a program to be educated. Some managers mentioned an apparent complacency amongst older workers and others commented on ongoing difficulties to get workers into the habit of wearing RPE despite their supposed increased knowledge and awareness.

> I know best…and it won't hurt me…that kind of attitude. And it tends to be the people who've been in the job for 20, 30, 40 years that have those kind of attitudes…those things have changed while they've been in employment, but they still behave in the way that industry did when they first started work and it's hard to get people to change behavior.

When asked what they considered to be the primary risks on their site, silica dust (RCS) was predominantly mentioned. Others included chemicals/vapors from work products (e.g., cleaners), welding/paint fumes, isocyanates, respirable enzymatic dust, grinding dust, and asbestos (in a few cases, a couple with very rare exposure). In some cases, non-respiratory risks were considered primary, such as noise and manual handling. Only managers in a few companies considered nuisance dust to be a primary risk. It is a concern that some managers did not equate nuisance dust with toxicity (e.g., where silica dust was present). Little thought had been given to the removal of general dust to obtain tighter control over harmful dust (a requirement of COSHH). As one manager stated, *"(Dust is) just an ongoing thing that happens"*.

8.4.1.2 Knowledge Base, Gaps, and Needs

Managers thought that they had good knowledge of the controls they needed to put in place to protect workers from respiratory disease and were generally aware of the HSE guidance. Managers felt that they and fellow managers had a good working knowledge of RPE stemming from one or more of the following:

- Personal use of RPE in the past.
- Learning from fellow companies in their group or competitors through the open sharing of information and seeing what RPE programs others have in place.
- Learning from external health and safety consultants, RPE manufacturers, and suppliers (3M was frequently mentioned) on how to follow RPE best practice set out by HSE.
- External publications (e.g., newsletters, magazines) and training.
- Industry bodies, including Union guidance and support.
- HSE events (e.g., organized conferences, presentations, and seminars), guidance, publications, and the website.
- Proactively seeking RPE information/advice (especially the quarries) and information on the latest technological developments.

> You're always searching round for good practice. We're members of various trade bodies and we'll attend various meetings so you do pick up tips, but it's perhaps a bit random.

While some managers commented on the high standard of RPE advice contained within the *HSE website*, a number of barriers to effective use were noted. These were: the need to enter specific search terms, which are not always known; difficulty navigating or finding information; guidance being too lengthy—*"Directors don't always have the time to sift through the information to find out what he needs to know"*; and little industry specific guidance.

> It's quite easy to get some quite obvious things, but then if you want a bit more detail it gets a little bit more complicated. You can put into the search engine in the top, I found it frustratingly difficult to get information.

Although some managers seemed to be quite well informed, it was clear that they lacked specific details on RPE. In essence, they thought that they knew more than they actually did.

> You think you know as much, you think it's a dust mask, how complicated can it be? But the face fit testing, even that throws up a few clever bits of advice, or a few pointers which might seem common sense.

Managers in a few companies recognized that they needed further RPE training and commented that they were *"always learning"*. In other companies, managers were only made aware of the shortcomings of their RPE program through the research, especially those in the manufacturing of composite components sector. Nevertheless, these companies were classified as "learners" and thus had recently started their journey to good RPE performance. Overall, key *knowledge gaps* were:

- The need for fit testing with paper and half masks
- The importance of workers being clean-shaven for a better RPE fit
- How to properly store and maintain RPE
- Updates on ongoing developments in RPE from the manufacturing side

In a few cases, it was apparent that managers had misunderstood the manufacturer's guidance on maintenance for a particular type of half mask. This had not been rectified in personal meetings between management and manufacturing/supplier representatives. A so-called "28-day disposable mask" was favored by some to reduce costs, avoid maintenance, and enable simple monitoring of RPE issue/stock. A blanket policy was to replace the mask at 28 days as managers were under the impression that the filter would last this long. There is evidently the need for manufacturers/suppliers to avoid this kind of labeling in the written instructions that accompany RPE to prevent such misunderstandings.

> This one takes away the onus of COSHH because it's a twenty eight day mask, you don't have to maintain it because it is a disposable mask that lasts for twenty eight days so as long as it's kept in its containers.

Differences among the groups are summarized here:

1. *Learners*: Overconfident in their own and their workers knowledge level. Unaware of certain health effects and critical aspects of RPE programs (e.g., fit testing). Aware of HSE respiratory guidance, but not in any detail and want HSE to educate them.
2. *Developers*: Focused on educating workers whilst recognizing that they as managers are always learning. Heavy reliance on external information, actively seeking HSE support/advice and through the HSE website.
3. *Fortuitous*: Different knowledge levels apparent at different hierarchical levels. RPE knowledge gaps, but aware that they do not know everything on the matter. Reasonable risk perception and good attitudes toward the safe use of RPE, but lacking management commitment.

4. *Proficient*: Good RPE knowledge base at all levels, but need updating on developments. Good risk perception amongst managers and workers with either partial or good knowledge of HSE guidance. Following HSE's hierarchy of controls, using RPE as a last resort. Committed managers who are proactive in seeking new RPE information and insights. Apparent shortfall in knowledge on maintenance evident.

8.4.2 Program Selection

This section details the themes that emerged through the analysis of managers' responses to questions surrounding the decision making behind their selected RPE program. More specifically, the factors that influenced their motivation to initially develop a program and those that influenced their actual choice of controls are detailed. Factors influencing managers' decisions on the effectiveness of these controls and any required updates are further documented. A flow chart is provided in Figure 8.4 that demonstrates this decision-making process. Few differences were discovered across sectors and company size.

Key findings include:

- Legislation and external audits by HSE, insurers, and industry groups were key motivators instigating initial program development.
- Managers relied heavily on external information sources/advisors to select suitable controls. RPE manufacturers and/or suppliers, consultants, HSE guidance and/or the website, industry contacts, publications and events, and sharing information with sister companies and/or competitors were all key.
- Some managers commented that the type of RPE recommended by their inspector was not practicable. Stonemasonry managers also commented that the Stone Federation did not provide timely information and updates.
- Medium/large companies were more likely than small companies to have a wider network of industry contacts and to monitor the HSE Website.
- Worker feedback, control availability, history of use, managers' own knowledge, experience and research strongly influenced the specific controls selected, supported by manufacturers/suppliers advice. Small companies in particular looked to suppliers to tell them what to do, bearing in mind what was affordable.
- Objective assessments (e.g., LEV monitoring) determined control effectiveness. Subjective assessments reinforced this, that is, worker observations/feedback, improved management self-efficacy and health and safety culture, and comparison with other companies (small companies) or previous performance (medium–large).

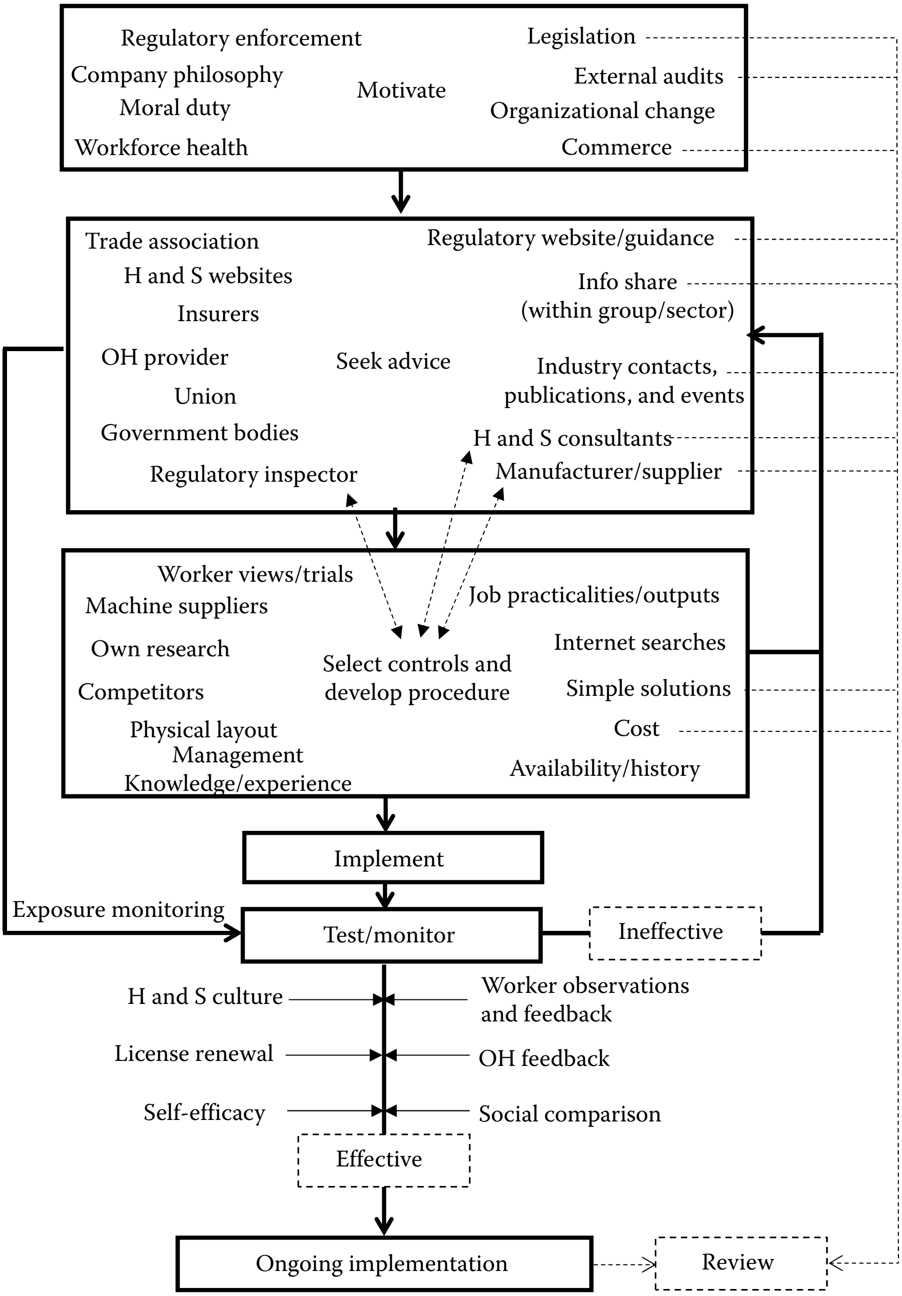
Regulatory enforcement
Company philosophy
Moral duty
Workforce health
Motivate
Legislation
External audits
Organizational change
Commerce
Trade association
H and S websites
Insurers
OH provider
Union
Government bodies
Regulatory inspector
Seek advice
Regulatory website/guidance
Info share
(within group/sector)
Industry contacts,
publications, and events
H and S consultants
Manufacturer/supplier
Worker views/trials
Machine suppliers
Own research
Competitors
Physical layout
Management
Knowledge/experience
Select controls and
develop procedure
Job practicalities/outputs
Internet searches
Simple solutions
Cost
Availability/history
Implement
Exposure monitoring
Test/monitor
Ineffective
H and S culture
License renewal
Self-efficacy
Worker observations
and feedback
OH feedback
Social comparison
Effective
Ongoing implementation
Review

FIGURE 8.4
Flow chart showing managers' decision-making process in RPE program selection.

8.4.2.1 Motivators of Program Development

Two key drivers were found to underlie the implementation of RPE programs. These were: (1) *legislation* or compliance with the law, and (2) *external audits* by HSE inspectors, insurers (to reduce premiums), and/or industry groups.

> It's best having the insurers back us up because they have a risk management team, so if we needed any new stuff putting in place they would help us with it…and then again the benefit is they should be able to reduce our premiums for us.

Other motivating factors, albeit to a lesser extent than those above, were:

- *HSE enforcement* with the receipt of an enforcement notice.
- *Following company philosophy/policy* as in following the company's health and safety plan/policy on RPE or had the philosophy of using RPE only as a last resort.
- *Moral duty* to workers or *"the desire to do the right thing"*.
- *Workforce health* was a driver for some managers from having experienced health-related claims in the past or knowledge of a previous worker becoming ill.
- *Organizational change* was an instigator (e.g., a new senior manager, company take over).

  > (A new Regional Operations manager) kicked off a program to look into the dust issue with a fresh pair of eyes …We just set down a road of just basically taking a look at it and see what comes out of the other end and quite a few things did come out of the other end.

- Commercial drivers (e.g., reputation, financial protection, smooth running of the business). "Now the commercial reason could be that if we don't do it we'll get sued".

8.4.2.2 Factors Influencing Choice of Controls

8.4.2.2.1 Information Sources and/or Advisors

> There's a plethora of guidance out there … half the problem is trying to decide what's relevant.

In order to decide "what is relevant", managers relied heavily on external information sources and advisors. In some cases, managers simply reacted to what they had been told to do. Compared with other sectors, manufacturing of composite components companies were more inclined to adopt this reactive approach to HSE inspector and/or health and safety consultants' advice.

> So we've developed relationships with technical bodies, with outside suppliers to give us the information that we can make the decisions on.

Five key information sources/advisors were:

1. *RPE manufacturers and/or suppliers* (including major PPE suppliers and machinery suppliers for specific work activities, such as welding): In some cases, representatives worked with managers to help them to develop site-specific RPE procedures or to help them solve RPE-related problems. Credible companies were considered to be a useful source of technical information, which managers were mindful of lacking themselves.

   > We certainly have gravitated over the years to firms who have reps who seem to know what they're doing.

2. *Health and safety consultants* (both internal manager/function and/or external consultants): These were often an information-gathering source explaining to managers what they needed to do to comply with the law, finding out what other companies were doing in the area, and keeping managers abreast of any changes in the legislation and updates in RPE design. Consultants also carried out exposure monitoring and site audits, sometimes providing technical recommendations in their reports. Through tapping into the knowledge and expertise of consultants, managers felt confident that they were adhering to best practice.

   > We just buy what they tell us to buy.
   > From our point of view being part of a big group and having the likes of (the Health and Safety Group Manager) and the experience there is a great asset, I don't know where we'd be without that.

3. *HSE guidance and/or website*: HSE guidance was generally accessed through the website. The website was thought to contain relevant, up-to-date, and accurate information, useful for helping managers to understand what they needed to put in place.
4. *Industry contacts, publications, and events* (e.g., organized meetings and seminars): These were considered to be a useful source of RPE-related information and a mechanism for sharing best practice. This was not always limited to "within sectors"; managers in the stonemasons took advice from publications or contacts in other sectors. They felt that the Stone Federation did not provide timely information and updates. Medium- and large-sized companies were more likely to have a wider network of industry contacts.

   > We attend a…meeting and that's with people from within the industry, so again you get a lot of information from everybody else from within the industry.

5. *Information share with other companies in the group and/or sector*: Sharing of ideas was common between companies in the same group as well as knowledge sharing with competitors. This social dialogue agreement with fellow companies was thought to encourage everyone in the industry to help one other.

> We have…group quarterly meetings where the Works Manager from each of our sites gets together and we have a visit to one of the sites and have a walk round with PPE…the Works Managers say, I've seen this at (place), is there any chance of us trying it?
>
> I've got quite a few numbers from peers in other companies, so I mean I've always said it's funny because on the production side of things nobody will share anything and you wouldn't be able to phone up the production manager (to) have a chat about production, but I can phone up the Health and Safety guy and we'll have a chat.

Other information sources/advisors included:

- *HSE inspectors,* although some managers commented that the type of RPE recommended by their inspector was not practical for workers to use for certain activities and was sometimes too expensive.

> I mean it was costing an awful lot of money and they are just sitting in there now…impractical.

- *Insurers* through their annual audits and recommendations.
- *Trade associations* (e.g., Cast Metals Federation, Engineering Employers Federation) who have their own health and safety departments or employ consultants to offer advice.
- Occupational health providers, unions, government bodies (e.g., the World Health Organization and universities) and general health and safety websites, some of which managers in small companies have paid for the privilege of using to access the documentation and guidance that they need.

8.4.2.2.2 Managers Own Research

Managers own research into the specific type of RPE/LEV required for the activities on site was a key factor influencing their decision making. This included consideration into what was practical for workers to use and the likely impact on the quality of work outputs (referred to as job practicalities/outputs in Figure 8.4). This generally involved examining the following balanced against exposure monitoring results and risk assessments and/or method statements:

- Manufacturers instructions (e.g., suitability to work processes, percentage of dust extracted)
- Worker tasks (movements they take, space worked in, etc.)

- The impact of controls on the quality of the outputs
- The feasibility of engineering solutions
- The work required to enclose RPE operations

Once completed, managers discussed their findings with RPE manufacturers/suppliers to select *"the best mask for the job"*. Suppliers often helped small companies to interpret consultants' recommendations in exposure monitoring reports by simply telling them what they need to do. In some companies, managers also confirmed their selected approach with their HSE inspector. Nevertheless, management knowledge rarely took precedence over advice from external experts.

8.4.2.2.3 Management Knowledge and Experience

Another key factor underpinning the selection of RPE controls, particularly LEV, was the knowledge and experience that managers brought with them from previous jobs.

8.4.2.2.4 Worker Involvement

Worker feedback on RPE and, to some extent, LEV trialed was found to have a strong influence on the specific type of controls selected by management—*"They're the guys actually using the equipment"*. Managers generally selected controls based on worker satisfaction and exposure monitoring results. Workers were typically not involved in the initial selection of RPE; managers selected these with manufacturers/suppliers. Managers perceived workers as having little technical RPE knowledge or knowing which types were appropriate for the activities they undertake.

> So you have got to make your purchasing decisions along with the guy's feedback … they're all much of a muchness for price so if the guy has got a preference and it fits him then we might as well go for it.
>
> I mean, when we trial them the guys have forms to fill out on comfort, seal and all that side of things.

8.4.2.2.5 Availability and History

Availability of controls and history of use within the organization were also found to be a key factor influencing choice of controls. In some cases, controls had been in place for many years and had evolved over time, often selected prior to current management being in post. RPE was often left untouched *"because it seems to work well with the guys that have them"*. This approach was more common among medium- and large-sized companies than small companies.

> They were certainly already in use when I started on the site 13 years ago.

The decision to try different types of RPE was also reliant on whether the company could easily access a supply of these, including the required filters.

In one company, a manager talked about deciding to use different types of RPE, as there was a stack readily available on site.

8.4.2.2.6 *Simple Solutions*

Some managers' choice of RPE program was influenced by their desire for a simple solution. For example, adopting the same approach as sister sites, producing a simple inventory for stock control, reducing time spent on multiple face fit testing with different masks, and dealing with more than one health.

8.4.2.2.7 *Cost*

Cost was found to play a role in some companies, particularly small companies (e.g., the three small brick making companies) that were more likely to be struggling in the recession.

> There's no two ways about it, the cost does come into things.
> I think we've got a lot of plans in place it's just getting them implemented … but at the moment everything is at a standstill because of money.

Some companies could not afford the most suitable type of RPE for their workers when single, expensive units (e.g., air powered respirators) needed to be purchased for each RPE operative. Others commented on the considerable cost involved in engineering operators out of hazardous processes.

> In an ideal world we'd have a fantastic robotic system in place that did all singing all dancing, but financially the cost of that is just so exorbitant.

In most medium- and large-sized companies, however, cost was not perceived to be a limitation.

8.4.2.2.8 *Peripheral Influencers*

The following were found to have a low-level influence on managers' decision making:

- *Competitors:* adopting controls that work in other similar organizations, possibly because knowledge of what others were doing was not readily available to them.
- *Internet searches:* general searches by managers to find suitable RPE/LEV.
- *Machine suppliers:* useful when job requirements change and RPE needs to be selected on an ongoing basis for new jobs, especially in construction companies.
- *Physical site layout:* the buildings infrastructure was commented on in some cases, either enabling or hindering the segregation of RPE activities.

> I think here you're limitations are the building…some of the buildings are old…like you were talking about putting more hoovers in place but that means more points.

8.4.2.3 Factors Influencing Perceptions of Control Effectiveness

A mixture of objective and subjective assessments determined whether managers considered the controls implemented to be effective in reducing worker exposure to respiratory hazards. Objective assessments included exposure monitoring results (e.g., pre- and post-LEV air sampling), fit test results (to determine the suitability/effectiveness of the selected masks), feedback from occupational health providers (when used) on the health of the workforce, absence of health-related claims, and (in one case) license renewal to work with asbestos. Subjective assessments reinforced findings from these objective assessments and had a strong influence on whether management considered their selected program to be effective or not. These were:

- *Worker observations and feedback:* To check that workers were using RPE when required, and using it correctly in some cases, and discussing with workers reasons behind noncompliance or misuse. Ongoing feedback from workers through informal or formal channels of communication (e.g., suggestion schemes, worker representatives at health and safety meetings) mostly concerned level of comfort and any practical difficulties experienced when carrying out work tasks requiring RPE. Formal feedback mechanisms were more prominent in medium and large companies than small companies.

> I mean they're the guys that are doing the job, they'll surely tell you if the stuff that you've got is right or wrong.
>
> We do a system called walk and talk which is where members of management go and literally have five or ten minutes talk with the operators, are things okay…, have you seen the risk assessment for this activity, are you aware of this and that, that gives you a chance then to actually … see what people are doing and are they behaving safely.

- *Improved health and safety culture:* Instilling a culture in which workers look out for one another or where everyone is working toward continuous improvement in controls.
- *Increased self-efficacy amongst managers:* Increased confidence in controls based on visual improvements (e.g., a reduction in dust), feeling more in-tune with HSE guidance, and in a stronger position of control than previously experienced, and having liaised with experts (mostly RPE manufacturers/suppliers and HSE inspectors) were all reported as positive influences on managers self-efficacy. One

manager commented, however, that they were disappointed when their HSE inspector discovered problems after they had taken advice from those they considered experts on the matter (i.e., suppliers).

> "We certainly moved up a level in that time" (compared with 8 years ago). I seek advice and to the best of my ability. I've ordered that equipment to protect the guys doing that particular job.

- *Social comparison:* The perception of being better than competitors and/or better than the standard implicit in industry. Small companies tended to compare themselves against their competitors, whereas medium and large companies tended to monitor their own progress over time.

8.4.2.4 Factors Influencing Whether the Program was Reviewed/Updated

Some managers were waiting to be updated on RPE developments to determine whether there was a better approach they could adopt or new equipment they could utilize. This often came from RPE manufacturers and suppliers, health and safety consultants, industry contacts, or from developments in other companies within their group.

> I think that could be improved … because we haven't touched the subject for two years (and) no doubt there will have been improvements in the design, weight, etc., … this month (RPE supplier) are going to come back … and do another straw poll for us and tell us what has improved. I think we had the best on the market two years ago… Has RPE moved on in two years?

Managers of medium and large companies were more likely to regularly use the HSE website than small companies to keep up-to-date on developments or changes.

> Where possible I look at the HSE website on an as and when required basis, I also get the HSE updates on a regular basis that come through which I circulate round and send off to risk control and … to all departmental managers.

Key drivers initiating a review of RPE programs were changes in legislation and recommendations from external audits (consistent with key motivators initiating program selection in the first place). In addition, business/commercial factors, namely, to reduce costs and complexity of the program (especially with regard to maintenance), were found to influence whether reviews were undertaken.

> Legislation drives decision-making … as limits come down, controls are put in place.

One manager commented, however, on their disappointment with their insurers for not keeping them abreast of changes in the legislation. This demonstrates the dependence that some managers have on their external advisors.

> When the HSE came in last time I was really disappointed, because we hadn't done as well as we should've done and I … think that sometimes you do feel let down because … we have an insurance company that we pay to come and inspect who didn't say to us, you should be doing (this).

8.4.2.5 Summary Flow Chart of Managers' Decision-Making Process and Influencing Factors

Figure 8.4 illustrates the stages that managers go through when selecting their RPE programs. The factors that influence this process are indicated at each level with the most influential highlighted in bold. Evidently, there is considerable overlap between the stages. For example, a range of factors at varying levels influenced whether managers updated their RPE programs. This review process was not, however, undertaken in all companies. Feedback loops between seeking advice, and selecting and testing controls were also apparent as managers generally consulted external experts at given points to help determine appropriate ways forward.

In effect, this flow chart represents the managers "mental model of the decision-making process that they go through when implementing RPE programs. It represents a simplified version of reality or managers" representation of their external reality.

Differences among the groups are summarized here.

1. *Learners*: Less likely to use a variety of information sources to inform their decision making and are thus not completely aware of all the options available to them. This creates problems when they do not use credible/known RPE suppliers. They are happy to have achieved an acceptable standard (in their mind), considering themselves to be better than they were previously or better than their competitors.
2. *Developers*: Looking for simple maintenance solutions and in general want a steer with their RPE programs, often looking to RPE manufacturers/suppliers for technical insights. In a few cases, a manager is a position of authority was instrumental in driving forward changes. Keen to learn from other companies, but tend to wait to be updated. This group is more likely to get involved in research projects like this.
3. *Fortuitous*: To some extent their decision making has been taken away from them as there appears to be little consideration to technical data amongst managers; happy to hand this over to a reputable external source, mostly RPE suppliers.

4. *Proficient*: Best practice guides their approach (through Industry/ HSE). More likely to use a wider contact base and be more proactive in their search for information to inform their decision making than other groups. Tend to monitor RPE/engineering updates (e.g., through the HSE website) internally and generally have a good level of health and safety resources to draw on.

8.4.3 RPE Use

This section details the themes that emerged through the analysis of managers' responses to questions surrounding RPE misuse amongst their workers. There was considerable consistency in the themes that emerged across the 20 sites with regard to the behaviors observed. Whilst no differences were found between sectors with regard to the approach taken to encourage behavior change amongst their workers, a few differences were discovered between small and medium to large companies.

Key findings include:

- RPE misuse was common amongst workers, with the exception of companies governed by tight procedures (e.g., asbestos removal guidelines).
- Managers considered misuse to be the result of an interplay of factors, most commonly cited were discomfort, doing a "quick job" (low exposure), stubborn attitudes amongst mature workers, not being able to see the hazard, and not having RPE to hand.
- Companies preferred a friendly, informal, education approach to behavior change, especially small companies. Medium- and large-sized companies had also developed formal strategies for encouraging compliance behavior including RPE policies/procedures, roles and responsibilities, structural modifications, communication channels, and disciplinary/reward systems.
- Some managers recognized the importance of cultural developments to promote use.

8.4.3.1 Misuse Observed by Management

> You think it's commonsense, how can you put (it) on wrong, but you find that you walk round and people do, they're upside-down or… not on properly.

The majority of managers commented on ongoing problems that they encounter with RPE use amongst their workforce. These included, but were not limited to:

Moving RPE away from the face to talk to colleagues or to check work in progress.

> They tend to do it when you're talking to them … they'll lift their mask up and put it on their head.

- Holding RPE over the face when carrying out quick jobs (e.g., sweeping).

> (They) just like to sit it on their face rather than actually fitting it properly.

- Only using one strap on a double-strapped mask.
- Not being clean-shaven when asked.
- Poor storage and maintenance habits (e.g., leaving RPE lying around and not using the bag/box provided, not cleaning/looking after it as told).

> (We've) had trouble with having to keep calling them (workers) back in and saying…we're giving you a bag, you've got to keep your bag, stop leaving them laying around…that was a bit of an initial problem… littering the site with them.

Some also mentioned that it was an ongoing battle for them to ensure that workers wore their RPE when required. The risk of this was considered higher in the summer or when workers completed "quick jobs", especially when team leaders/supervisors were not present.

8.4.3.2 Perceived Reasons for Misuse

The majority of reasons given by managers for RPE misuse rested with the worker, namely:

- Discomfort (restrictive, sweaty), especially over long periods of use.
- Mature workers not used to wearing RPE questioning why (stubborn attitudes).

> Research does show that you tend to get sensitized within the first two years for enzymes, its high molecular allergens…the highest rate of sensitization is within two years of starting the job… I think a lot of our long termers are very much of the mindset that it won't happen to me, I've been here so long.

- Not being able to "see" the hazard.
- Perceived low exposure in quick jobs or for outdoor work on a windy day.

> The worst ones are very quick jobs … so fast it's not worthwhile putting RPE on.

- Not being able to see an immediate effect on their health (long latency issue).

- Considered inconvenient if not nearby or in hand (some alluded to laziness).
- Forgetfulness during low frequency tasks or being distracted (e.g., out of work stresses).
- Disrupting work processes (e.g., through restricting vision).
- Workers seen to resist anything new.

> I think with anything new, especially on health and safety, everybody puts up a fight to begin with.

- Have a propensity to take risks (like smokers).

> They know the risks but do it anyway.

Some managers were, however, aware of organizational-level failings that contributed toward misuse or noncompliance. These largely reflected a lack of clear RPE processes and procedures (e.g., lack of clarity over when exactly RPE should be worn, accounting for all work processes, and not keeping RPE records of issue), poor communication with workers about RPE (e.g., barriers when workers' first language is not English, rarely discussing RPE in meetings/briefings), absence of fit testing or lack of training on fit and care, and lack of supervision.

> Spraying is black and white, when you spray, you need the RPE on. (But what about the shades of grey, such as standing near a colleague who is spraying?)

8.4.3.3 Behavior Change Strategies

In general, management preferred to adopt a friendly/informal approach to enforcing RPE use, particularly in small companies where they had established a close rapport with workers and wanted to retain directly employed staff. In these cases, disciplinary action was considered a last resort after a substantial "teething" period in which managers focused their attention on educating their workforce. This was accomplished by managers/supervisors talking to operatives on a regular basis, making them aware of the dangers and why it is important for them to wear RPE. The philosophy underlying this approach was to gain worker buy-in and encourage habitual use.

> What we've said here is that we'll leave it for a bit longer and keep gently pulling people up on it, what we did at the other sites was we then put up a notice that said you've got a month from today to vent any issues and then once that month has lapsed anybody not abiding by it will be subject to disciplinaries.

Managers generally asked workers to be clean-shaven, as they felt uncomfortable creating a clean-shaven policy; some questioned whether they would actually be allowed to do this.

> We don't demand (that) people are clean shaven, what we do is explain that they're unlikely to get a satisfactory fit … and then if they do need respiratory protection, then one that relies on a tight fit probably won't be suitable. And generally people will cooperate.

Some companies, mostly the medium and large, had developed formal mechanisms through which management encouraged compliance behavior. This involved utilizing formal communication mechanisms between management and workers (e.g., signage, committee meetings, training), developing standard RPE policies and procedures (e.g., designated RPE areas/activities, site audits, management health and safety targets, and job rotation), implementing disciplinary and reward systems (although the former was more common that the latter), carrying out structural modifications (e.g., an office move to monitor workers), and establishing clear RPE roles and responsibilities (e.g., clear channels to report RPE problems). In one company, behavior change was not deemed necessary as all workers were complying with the strict asbestos removal procedures that were in place.

> … Whereas before it was a little bit like…you have to wear masks and it was kind of, well where do we have to?…but now it's like this area is a dust mask area.

Some managers also highlighted the importance of culture change to overcome old school attitudes prevalent amongst workers and encourage compliance behavior. Managers commented on developing a family business culture in which workers consider one another's health and influence each other to wear RPE. In some cases younger workers were being targeted to encourage this culture change.

> Today these lads have got it dqt1rilled into them and they realize the problems and what it can cause.

Differences among groups are summarized here:

1. *Learners*: Assume that workers know how to correctly wear RPE, but encounter ongoing problems with getting some of them to wear it. Worker misuse is largely the result of management inadequacies (e.g., unaware of the need to fit test certain types of RPE). The basic approach is to tell them to wear a mask; *"They have been told what to do and they are expected to do it"*. Managers perceive that misuse rests with the workers.

2. *Developers*: Adopt an "educate workers" approach to encouraging RPE use with little enforcement. Persistent in educating workers. Thinking of bringing in disciplinary and reward systems and acknowledge that they could do more at the organizational level (e.g., provide more training).
3. *Fortuitous*: Quick to intervene and discipline workers when they see RPE misuse on site. Speculate about the reasons for misuse, but do not take proactive action to find out the true reasons behind this and act accordingly.
4. *Proficient*: Set RPE standards and procedures being followed and commitment to preventing misuse. Supervision in place to varying levels to monitor use. More likely to have developed their health and safety culture and communications over the years compared with other groups.

8.4.4 Training and Advice

This section details the themes that emerged through the analysis of managers' responses to questions about RPE training and advice for workers. More specifically, the types of training and information that managers provide to their workforce and reasons for adopting different approaches are reported. Current gaps for both workers and managers are also discussed. Some differences were found between small and medium to large companies, but very few sector differences were discovered.

Key findings include:

- Companies used a variety of means to communicate the importance of wearing RPE or to provide updates. But in the foundries little to no RPE-specific information was given perhaps because other health and safety issues took priority.
- Very few companies had a formal program in place. Those that did tended to be medium–large companies and covered all health and safety issues.
- RPE inductions were commonplace, often through a supervisory briefing.
- Refresher training was rare as managers felt that RPE was common sense. Small companies often did not have the resource to support this. Toolbox talks were the preferred means of refreshing knowledge when done.
- Manufacturers' instructions accompanying RPE were not considered to be user-friendly.
- Key training and information gaps were communicating to workers the importance of a good fit, being clean-shaven, and how to properly maintain RPE.

- Managers wanted more HSE training, guidance and support, frequent independent advice from HSE, insurers and consultants, closer links between HSE and intermediaries, an "intelligent advisor" approach of inspectors and further research.

8.4.4.1 Types of Training and Information Provided

8.4.4.1.1 Training

Very few companies had developed a *formal training package* for workers. Those that did tended to be medium to large that delivered health and safety training covering all site working procedures and health hazards (including PPE/RPE). These tended to be delivered by health and safety advisors/managers rather than supervisors on the shop floor.

> We made the assumption that our employees understand what silica can do to them but perhaps some of them didn't, so the training package was put together which gave an overview of, this is what happens to you and… perhaps you could argue there was a little bit of scare tactics… but it certainly made sure that everyone knows why we were doing what we were doing.

Very few companies put their workers though *external health and safety training courses*. Those that did had heavy union involvement or National Vocational Qualifications were a requirement for the job and covered RPE.

> We don't have any sort of training certificates, we don't send them on any particular courses, it is something that we don't feel is necessary. We believe that the instructions that I have from here is adequate for their use of it (RPE).

In the majority of companies workers were given some kind of *induction* to their RPE when new to the job or when first introduced to it. In some companies (particularly medium to large), a formal induction or health and safety session was delivered, which incorporated RPE. In others (particularly small companies) RPE tended to be covered through on-the-job instruction or task specific training by supervisors and was therefore more process or equipment focused with RPE explained as appropriate. Inductions in metal fabrication companies focused on the equipment required for different tasks. Supervisors or team leaders in these companies were more likely to discuss the technical properties of RPE/LEV with workers than those in other sectors.

> They're originally given training on everything related to their work area, so we split the factory into four areas, each area has got its own manual and they have to go through the noise survey, the dust survey…so they're trained on what job roles require what PPE. For the mask they're told which mask is suitable…it's explained to them on how it's to be worn.

> We would do toolbox talks…the shorter perhaps more punchy informal training.

Both formal and informal inductions generally covered basic information on RPE and LEV use, namely, requirements for different work tasks, reasons for use (focusing on the hazards), how to obtain RPE, how to correctly use LEV/don RPE, and the reporting of problems with equipment. Such training was generally felt to be effective, having a positive impact on operatives' acceptance.

> When somebody starts working for the bagging plant they go through all of the risk assessments for the bagging plant, the procedures that they need to work to and part of that training is how to wear the respirators and what to do when.

In companies that arranged *fit testing* for workers either through manufacturers, suppliers, or in-house through a manager trained to carry this out, RPE inductions tended to cover all aspects of RPE programs. This included how to ensure correct fit, common RPE failures, storage and maintenance procedures (cleaning, how to test and change filters, testing air supply, etc.).

> It's covered as part of the face fit testing… even just giving them a bit of advice about making sure that the headband one is behind your crown and one's behind your neck…things like that, it just makes people think that… it's in the right place, they actually check that it's fitted.

Refresher training was generally not formally carried out; reasons included:

- RPE being "common sense" and therefore not necessary to remind workers.

> *(It's) like training someone to put on a pair of gloves.*

- Confidence that workers know the risks and their kit as they use it every day.
- A fear of overwhelming or confusing workers by providing too much information (especially small companies).
- Annoying workers with frequent reminders was thought to hinder compliance (especially small companies).
- Lack of resources in terms of the staff availability and time to carry it out (especially small companies).
- Workers did not use RPE frequently enough to justify training.

> It is harder to do it on a proactive, pre-emptive basis than it used to be, just purely because there just isn't the numbers of people available on there to gather everyone together and … you end up doing a toolbox talk with one or two people and it just can become difficult to just physically organize having several people in one area, just how things are.

Refresher training is often resource intensive to organize and prepare. It was therefore more likely to be carried out in medium and large companies than small companies. For example, a manager from one company that provided refresher training to workers commented:

> Asbestos training has to be renewed every year … it's hard to put experienced guys through the training year upon year, upon year.

The reason for including refresher training in this company was mainly driven by tightly controlled procedures being followed for asbestos removal, but also to protect the company against workers selecting and using incorrect RPE.

Some companies alluded to delivering informal reminders and updates through toolbox talks (weekly or monthly) or site walkabouts. One manager said that they informally questioned workers on RPE and provided a refresher if their knowledge was considered to be below par.

8.4.4.1.2 Information

Written material provided to workers on RPE included leaflets, booklets, and information posted on the Intranet and/or attached to notice boards. This information generally covered best practice when working with hazards, types of RPE available, when RPE needs to be used, and how to set up LEV/use RPE (a reiteration of the information conveyed through formal or informal inductions).

> We have the intranet, which has some information…I know there's information on why we do the dust sampling… We've got site specific health and safety manuals and each employee has a CD copy of the company health and safety manuals.

Some managers commented on the company's occupational health doctor/nurse providing information to workers (e.g., HSE guidance on respiratory disease, a letter explaining silica risks, symptoms, and health surveillance). Memorandums were also used to communicate any updates to RPE programs in medium and large companies. Managers acknowledged the advantage of issuing such written guidance to workers in companies where they had a diverse workforce. Those in small companies also commented on the need to make sure that information is adequately tailored to the workers' level of understanding and needs, and appeared to be more in tune with this than medium and large companies.

There were a few cases, however, where the written material provided to workers was not reinforced with briefings or demonstrations by managers/supervisors. Workers were simply given a health and safety file or booklet covering RPE/PPE and expected to read this. In the worst case, workers were told to read the manufacturer's instructions that accompanied the mask.

Reasons for adopting a purely written approach mirror those given for not providing refresher training in Section 8.4.4.1.1.

> We show them any notices we get…or anything we pull up go up on notice boards and things like that, but then they've got to interpret it.

In the foundries that participated in the research, little or no RPE-specific information was provided to workers, perhaps because other health and safety issues took priority. In general, however, companies used a variety of mechanisms (verbal, written, and visual) to communicate the importance of wearing RPE and to provide workers with updates. This was more evident in medium and large companies than small companies, possibly a reflection of greater resource in the former. Other types of *visual information* utilized included HSE/manufacturer posters, point of use prompts/signs, and videos. A few managers were in the process of developing innovative means, such as videoing staff wearing RPE and posting this on the Intranet and displaying information on a TV screen near the canteen area. Both of these received positive feedback from workers. In the latter example, managers commented that workers discussed RPE and asked more questions than they did prior to these interventions.

> You'd see the TV on … and probably RPE would be a subject, so we sort of do that and we've got monthly briefs so that we can pass on information like that.

It was recognized by most managers that workers would not want to read the company's *formal health and safety documentation* (e.g., risk assessments, COSHH assessments), but these were made available to workers through an open-door policy should they want access.

8.4.4.2 Training and Information Gaps for Workers

Some companies recognized that they could do more with training workers about *the importance of good fit, including the need to be clean-shaven*. Formal fit testing was seen to be the best method for achieving this. The area of RPE programs that presented the biggest gap in terms of the quantity and quality of training/information provided to workers was *maintenance of the kit*. This was consistent across the 20 sites and even represented a gap in companies that provided fit testing. Although basic information was provided, good maintenance generally relied on good operator judgment.

> I'm not quite sure whether it covers the maintenance of the respirator but it tells them what to wear when.

There was also little evidence of training being *formally documented and monitored*, despite formal training programs being delivered in some cases.

8.4.4.3 Training and Information Gaps for Managers

Insights into the types of training and guidance that would assist management in improving their current RPE programs were gained from asking them about further RPE-specific support that they would like from HSE or elsewhere. Only one manager out of the 40 who participated in this research felt that he did not require any more information or support. The following themes emerged from the remaining 39 managers:

1. Further HSE training, guidance, and support through:
    - Delivering seminars on RPE including demonstrations to educate managers. HSE is preferred to other external sources as it is regarded as impartial.

> There are an awful lot of seminars on silica and dust but there's not really anything on RPE…I'd like to see something… almost like a road show … with … exhibitions and things.
>
> I'd like to see somebody that's not biased give … an opinion on it really.

    - Setting up an RPE forum (company representatives, RPE manufacturers, designers, suppliers).
    - Conducting more site visits/inspections to clarify that companies are taking the right approach. A manager at one of the quarries thought that more inspections needed to be carried out in smaller quarries to encourage "a level playing field".
    - Providing simple guidance (i.e., shorter versions of full guidance), in particular, RPE tips and guidance on what specific masks are suitable for different work tasks, how they work and how effective they are, what best practice involves for each stage of RPE programs, and preferably, industry-tailored guidance.

> Directors don't always have the time to sift through the information to find out what he needs to know.

    - Sharing of case studies to communicate the types of RPE that other companies use, the programs they have put in place and found to be effective. A benchmarking service would be a huge motivator for some companies.
    - Providing guidance to managers on how best to train their workers and materials that managers can use in training, such as a handbook of industry hazards (e.g., isocyanates, chemicals, foams, etc.), a dust/paint/welding pack (like the noise pack), RPE DVDs, and materials for toolbox talks. DVDs were considered

by some managers to be a powerful mechanism for motivating workers to wear RPE.

> We've got a noise folder from HSE that we ordered which is just a training pack, its toolbox stuff, and it would be nice to see something for dust… At the moment we have to put all of it together so we have to interpret our report, interpret the legislation and pull some sort of training together and it would be nice to have a pack.

- Making the HSE website more user-friendly. While some managers commented on how good the advice contained within the HSE website was as a source of RPE information, a number of barriers to effective use were mentioned. These were: the need to enter specific search terms that are not always known, difficulty navigating or finding information requiring time and patience, and not being able to find industry specific guidance.

> I found it frustratingly difficult to get information.

2. Further research and development: One manager mentioned the need for developing an understanding of the typical ranges of RPE protection during exposure monitoring in the "real world" rather than the laboratory. This would help managers to be clear about the exact level of reduction in exposure that RPE provides to workers. It is a concern that this manager was unaware that HSE's RPE selection system was developed around protection levels in the field.

> Obviously, you assume they're well below an exposure limit if they're wearing the respirator, but it's an assumption.

Comments were also made about the need for greater research and development in RPE manufacturing.

3. Closer links between HSE and intermediaries (e.g., offering employers a contact/phone number to discuss health and safety concerns).
4. Independent advice: HSE, insurers, and independent consultants were considered to be the only independent sources of advice and preferred to RPE suppliers. In particular, guidance was sought on the best engineering controls to implement, bearing in mind the complexity of issues faced by different sectors, balancing exposure levels against the cost of solutions.
5. The approach of HSE inspectors:
    - Acting more as an advisor rather than enforcer in deciding with managers what is feasible, what specific RPE/LEV would be suitable, etc. This would require inspectors to have industry specific knowledge in order to recommend practical RPE solutions.

- Linked to the above, managers emphasized their desire to contact their inspector (or HSE generally) without feeling that they are exposing themselves to potential enforcement.
- Creating realistic expectations at the start, ensuring that managers know what is involved in the whole process (from selection through to maintenance) to avoid later frustrations.
- Consistency in approach (e.g., not opting for the highest level of control when it is not always necessary).
- Encouragement: a "pat on the back" from inspectors as companies make improvements.

Differences among the groups are summarized here:

1. *Learners*: Poor standard of training overall (quality and quantity) with little information provided to workers on how to properly fit RPE and maintain it. RPE was considered simple to use and not necessary to explain to experienced workers. Greater onus was placed on workers knowing or finding out for themselves. Senior managers had little knowledge of what was in place for workers. Some inconsistency was apparent in training documentation.
2. *Developers*: Recently introduced or were thinking about introducing more formal training. Generally provided information in a format that workers understood, using a mixture of communication means. Little appreciation for the importance of refresher training, inconsistencies in training documentation, and poor provision of information on storage and maintenance.
3. *Fortuitous*: No RPE-specific training provided to workers, just ad hoc, quick reminders to wear RPE for certain tasks. It was fortunate for these companies that workers were knowledgeable about RPE.
4. *Proficient*: Used a variety of communication means, some innovative measures. Included RPE in toolbox talks and were more likely than other groups to have well-established training systems in place, including refresher training. Acknowledged in some cases the need to provide more information to workers on maintenance and keep training records.

8.4.5 Ongoing Monitoring and Maintenance Systems

This section details the themes that emerged through the analysis of managers' responses to questions concerning the ongoing monitoring and maintenance regimes the companies have in place. This was an area in need of further development for the majority of participating companies. No differences were found across sectors or company size. Few differences were also found between groups ("learners", "developers", "fortuitous" vs. "proficient"). Although "proficient" companies were more likely to have monitoring and maintenance systems in place, there was room for improvement.

Key findings are summarized here:

- Insurers were a key driver behind implementation of systems to record RPE issue and worker health through health surveillance (not always required by law).
- Managers were often opting for simple solutions, ideally no storage or maintenance through using disposable masks where possible. Resource was a key barrier to ongoing maintenance of RPE and LEV. Companies were generally without standard procedures for storage and maintenance and rarely enforced poor practice in both areas despite this being commonplace.
- RPE maintenance was often left to worker discretion, which seemed to reflect a lack of clarity of good practice amongst managers.
- Some managers found manufacturers' instructions difficult to interpret and put into practice; they sought prescriptive advice on what to do in their workplace.

8.4.5.1 Factors Influencing Systems for Monitoring RPE Provision and Worker Health

Most companies had implemented a system whereby workers signed for new RPE upon issue. The motivation to do this mostly stemmed from their insurers.

> (We've) got a fairly good control system in now where (as) before it was just literally everybody helped themselves to PPE or whatever. They literally now have to come up through their (supervisor) and sign for the bits of kit that they take.

Similarly, insurers were a key-driving factor for managers implementing health surveillance for their workers, particularly amongst those who had a history of health claims (mostly non-respiratory related). The other driving factor was legislation (or being told by their HSE inspector), which specified this requirement in some companies (e.g., where exposure to silica dust was a risk).

> I think it's just merely the case of if we did have people developing any industrial type injuries our insurance will either become unaffordable or – we pay a very, very heavy price insurance wise…we understand that if we can protect the guys and they did get an injury and had to make a claim, commercially wise it would be catastrophic.

In a few cases health surveillance was not strictly required, but managers had implemented this as a protection measure following discussions with their insurers. In particular, management was keen to carry out pre-employment medical tests (including lung function tests) with new workers to guard the company against future health claims relating to workers' previous employment. One manager talked about the frequent review of new starters in their first few months of employment.

> New starters get reviewed over a shorter period during their first few months.
> They (insurers) like the fact that we do health surveillance … their view is you're ticking a box, you're doing a pre-employment medical, and you're doing a regular medical.

The provision of health surveillance was reinforced by positive feedback from workers and from managers themselves realizing the benefits from liaising with occupational health professionals (e.g., finding out what other companies were doing, a useful additional mechanism for obtaining worker feedback on health and safety matters, including RPE). Nevertheless, these benefits seemed to depend on a certain degree of trust being developed between all parties involved.

8.4.5.2 Factors Influencing Systems for Monitoring RPE Storage and Ongoing Maintenance

In general, RPE (new and replacement parts/filters) was stored in a place that was easily accessible to workers. Managers believed that easy access was a key factor influencing worker compliance. Following guidance from RPE suppliers, companies were providing the appropriate means of storage (e.g., a sealable plastic bag or container, personal lockers). Managers recognized the importance of proper storage (i.e., in a sealed container/bag away from contaminated areas) and maintenance to keep RPE fit-for-purpose and to extend the life of the kit. Some companies issued their own plastic boxes for workers, as they were aware that the plastic bags provided with the masks had a limited shelf life.

> It's about the fact that to be its most efficient it's got to be maintained.

It was evident that management wanted to make RPE storage and maintenance as simple as possible for workers (and themselves). In some cases, disposable masks were supplied to avoid the need for both storage and maintenance. In others, a maximum time was allowed for replacement (e.g., every 18 months) or masks were labeled with the filter replacement date. These managers generally relied on manufacturers' instructions to determine filter change and mask replacement dates.

> The beauty of these [half] masks is that they are low maintenance.

For some companies, ongoing monitoring of equipment was considered difficult due to a lack of spare labor to maintain RPE/systems and/or the cost of ongoing LEV servicing (by consultants). Managers in other companies, however, believed that their RPE and LEV systems were being properly maintained due to rigorous monitoring by external consultants (quite frequently in some cases, e.g., monthly) and/or insurers (usually annually or biannually).

Nevertheless, managers generally spoke of what workers "should" be doing based on what managers had told them rather than on what they were actually doing.

> They should put them in the locker… if they're going for their dinner … but between shifts they should put them away.

In many cases, workers had been given very little instruction about how to properly look after their RPE when disposables were not in use (e.g., when to clean them, change the filters, and replace the mask). Ongoing maintenance of RPE was frequently left to operators' discretion and managers noted considerable variability amongst their workers. Yet very few companies had a formal policy on RPE storage and maintenance because it seemed that managers themselves were unclear on what to do. Some commented on the difficulty that they encountered finding information on maintenance in HSE and the lack of clarity in manufacturers' guidance (e.g., uncertainty over the required frequency of checks in cases where RPE was used daily for a short amount of time).

> I mean the only information you can get from the HSE website is to have a monthly check on the air you put into that (air-fed system) … I don't know whether there's any kind of calculation that you could do to say… get an assessment, twice a year maybe… or something like that.

There was also little evidence of regular supervision or enforcement of poor storage or maintenance. Supervision tended to focus on RPE misuse or non-use with storage and maintenance taking less priority, despite most managers being fully aware of the poor practice happening on the shop floor.

Some management *misunderstandings or misconceptions* were apparent, namely:

- About the dangers of storing air-fed visors directly next to the machines
- A belief that ongoing monitoring is not required, as the risks do not change and workers are constantly aware of these
- Maintenance is considered unnecessary in a low exposure environment
- About the need for workers to change their RPE prior at the point where they can taste the dust or smell the fumes

There were a few exceptions where good supervision and maintenance systems were in place (e.g., regular RPE inspections by supervisors, daily logs maintained). Not surprisingly, these companies were categorized as "proficient".

> We do a lot of monitoring, personal monitoring so it's (silica dust) always in people's minds that it's a hazard.

Not all "proficient" companies, however, had a good level of ongoing monitoring and maintenance. Some were considered "acceptable" as they either did not provide a sufficient level of information to workers on RPE care or had no formal maintenance documentation to demonstrate regular checks. In one company, management had not implemented a system to ensure the ongoing testing of workers air-fed kit.

> There is an audible alarm to indicate a problem and the need to change the filters … they're (air-fed) pretty maintenance free really.

8.5 Worker Observation and Interview Results

This section presents the key themes that emerged across the observations and interviews with workers (or RPE operatives) during the site visits. The findings address, in part, the following objectives for this research set out in Section 8.1.2:

- *Objective 2*: Assessing the adequacy/suitability of the RPE selected and determining the factors influencing RPE use and care (storage/maintenance).
- *Objective 3*: To corroborate findings from the management interview with worker perceptions of RPE information/training provided, risk perception, and understanding of respiratory health risks. In addition, comparing observed practice on the shop floor with good practice.
- *Objective 5*: By identifying the enablers and barriers to effective RPE use and ongoing care.

Results from the worker observations and interviews have been compared with findings from the management interviews to determine the consistencies (between what managers and workers said or did) and highlight any inconsistencies in findings from the three data sets. Crosschecking data this way helps to build a clear picture of what is actually happening in practice. Furthermore, a more accurate estimate can be made of workers knowledge and understanding of respiratory risks by observing them in practice and asking them directly about observed behaviors. Any sector and/or group differences ("learners", "developers", "fortuitous" vs. "proficient") are highlighted. Where possible, quotations to annotate the comments made by workers are included.

A summary of key findings is provided here:

- On the whole, results supported findings from the management interviews. There were, however, some aspects that managers were unaware of or had misjudged, including:
  - The potential influence of the immediate physical benefits (e.g., no stiff chest) of wearing RPE on worker behavior.
  - Some concerns amongst workers over whether the correct RPE had been chosen.
  - The suitability of RPE was often not ideal, mostly due to the absence of fit testing. In some cases, ideal protection had been rejected due to high cost or worker preferences.
  - Some workers who had received little RPE guidance wanted further information.
  - The common belief amongst workers was that they are invisible whilst wearing RPE, even if not correctly worn.
  - Posters and written RPE documents were largely ineffective communication means.
- None of the sites visited were achieving optimum control through the use of RPE.
- Lack of clarity amongst *all workers* on correct storage and maintenance stood out.

8.5.1 Factors Influencing RPE Use and Ongoing Care

Considerable overlap was found between worker behavior and explanations of influences on their RPE use including ongoing care of their kit and managers' perceptions of this (as documented in Section 8.4.3).

- Being *threatened by the law* was a driver for influencing workers to wear RPE in some companies. This is not surprising as managers themselves were primarily motivated to implement RPE programs to comply with the law.

  > (We are) told to do it as it's law.

- Some managers had an *unrealistic perception of workers understanding of the health risks*, particularly those belonging to the "learners" and "developers" groups. These managers placed too much emphasis on workers already being aware of the risks when they were often unaware. There is evidently the need for all managers to better communicate health risks to their workforce, ideally through risk awareness training in companies where this is not already being conducted.

- The majority of workers considered RPE to be easy to use, but *those who had not undergone fit testing had a poor concept of fit*. Comments such as *"it's near enough"* and *"it seems to fit okay"* highlight the poor understanding of the need for proper fit. While management sometimes assumed that their workers knew how to properly don RPE, in practice they often lacked such knowledge or had made their own alterations rendering the mask useless.
- Proficient companies had *established RPE policies and procedures* to ensure that workers donned RPE when required (e.g., listing specific activities requiring RPE or segregated mandatory areas). Workers belonging to the "developers", "learners", and "fortuitous" groups were unsure whether a disciplinary system existed. These workers commented that their colleagues were not always following RPE policies (e.g., for storage), but not being corrected by management.

> It's very obvious when a mask is required – if not cutting (there's) no need.

- In companies where RPE standards and procedures were not in place, workers used their *personal judgement* to decide whether or not they needed to wear RPE for given tasks. This was generally considered to be "common sense" and was often based on sensory information in the work environment (e.g., seeing, tasting, or smelling the dust/chemicals).

> (You) can smell the iso's (isocyanates) in the air.

- A common finding was that workers considered the donning and correct use of RPE (particularly filtering facepieces and half masks) to be trivial, and that *training in how to fit the equipment was an unnecessary waste of time*. But, improper fitting to the extent that protection was likely to be compromised was commonly observed.
- Regardless of whether any RPE standards and procedures were in place workers generally *did not wear RPE for quick tasks* either because of the limited exposure time or to avoid the extra time and effort of donning RPE.
- *Comfort* played a role in determining whether workers donned RPE when required. Those who commented that they were happy to wear RPE generally considered their mask to be comfortable.

However, these workers were often using RPE for short periods at a time. Those wearing RPE for long periods each day commented on the following: difficulty breathing during manual tasks, or during hot weather, or when suffering from a cold; top straps of half masks cutting into the ear; finding full face masks heavy/cumbersome; and a preference for a small mask in confined spaces.

> (It's) uncomfortable and cumbersome to wear (half mask)
> (It's) okay to wear for short periods.

- *Considerable variation* was found *in the level of training received* by workers ranging from nonexistent to exemplary, the latter being in sites where there had been a high level of past involvement with HSE. Those in "proficient" companies had received training that went beyond a simple induction on how to use RPE to being fit tested, receiving other training covering respiratory issues (e.g., silica training) and, in a few cases, refresher training. In other (non-proficient) companies, there were some good examples of training and information for workers, but these aspects had not (yet) impacted on workforce practice.
- *Wide variability was noted for the storage of RPE*, particularly during breaks. This ranged from workers keeping RPE with them (e.g., around their neck) to leaving it hung up beside or left on their work bench/area. It was only at the end of the day that workers claimed to put their RPE away in the protective bag/box in a designated area. In line with findings from the management interviews, workers in general had *received little information on storage and maintenance*. Common sense was being relied upon for the ongoing care of RPE. There were uncertainties amongst *all* workers about correct storage and maintenance procedures (in most cases policies for these had not been set, see Section 8.4.5.2).

> (I received) a lot (of training) when first introduced three or four years ago, (but) not much refresher (training), not a lot on filters.

- When asked how they would feel *if they got ill because of their job*, those saying that they would be angry as they had done their best to protect themselves were in the minority. Most workers either had *not thought about it or did not care*.
- Workers in the *"proficient" group* commented that *management provided consistent messages on the importance of RPE use* through, for example, daily briefings. They were also aware that should management observe any acts of noncompliance immediate action would be taken, usually following a disciplinary process.

> Everyone knows (that) management take it (RPE) seriously.

Those belonging to either *"developers" or "learners"* generally perceived managers as *having a moderate level of commitment at best*. This seemed to be a reflection of delivering inconsistent reminders, lack of a formal monitoring system, and little if any enforcement of correct RPE use.

- *Practical supervision of RPE programs was* almost universally *poor*. This was often due to lack of clear responsibilities and detailed knowledge of those supervising to the extent that they did not recognize bad practice, or did not act on it. This lack of workforce clarity over good RPE use and care appears to have been underestimated by managers.
- *Workers belonging to "proficient" companies were more likely to have been involved in the RPE selection process* (often through trialing different masks) or, at the very least, had undergone fit testing compared with those in the "learners", "developers", and "fortuitous" groups.
- *Fully documented procedures describing the RPE program were rare*, only being properly established where there was either a clear statutory need (e.g., for asbestos licensing) or where there had been a significant history of HSE involvement. In general, *records of maintenance and testing* (as required by COSHH for all forms of RPE which are used for more than one month) *were lacking or completely absent*. Although the absence of such records does not invariably indicate that RPE is not being maintained in effective condition, it indicates that formal systems are not in place to demonstrate that maintenance is being kept under control.
- Nevertheless, it was apparent in worker observations and interviews that managers were either unaware or had misjudged the impact of the following factors on worker behavior.
- *Protecting one's health*, particularly common among foundry workers, was a motivator to wear RPE. This seemed to stem from their knowledge of a family member or colleague who had suffered a respiratory illness through work. Of most importance, however, was noticing the immediate physical benefits of wearing RPE by feeling better during and at the end of the day (e.g., no cough, stuffy/black nose, stiff chest). The latter was particularly apparent amongst workers in metal fabrications sector regardless of their time spent using RPE each day and their time in industry.

> I) immediately notice the effects…go home not stuffed up.
>
> (I) want to stay healthy…(my) Dad died young from miners' lung, aged 53.

- Although workers generally trusted management to select the best type of RPE due to not knowing any better themselves, a few were concerned about the type of mask that they had been provided as they saw dust in their mask at the end of the day. They had not, however, voiced this concern to their supervisor. In numerous instances the *suitability* (i.e., matched to the wearer, the working environment, and the task) *of RPE was not ideal*. This was mostly due to the absence of fit testing and workers not being clean-shaven. In some cases, ideal protection had been considered but rejected due to cost or worker preferences.

- Managers in (non-proficient) companies that did not provide training to workers considered RPE to be common sense, but not all workers felt the same. Of those who had received very little or no training, *some wanted further information* (e.g., health effects of hazards, RPE use).
- *RPE invincibility* was common amongst workers, that is, the belief that they are protected by simply wearing RPE, regardless of whether it fits or is operating correctly. Compliance with simply wearing RPE (however badly) created a feeling of being protected and any chance of getting ill through work was therefore perceived to be low.
- Static *posters*, even the most recent HSE poster giving donning guidance, *did not appear to be effective* in getting the message across to RPE wearers, they tended not to be read, and quickly became ignored. Simply issuing documentation to workers, or locating information folders in the workplace, had a similar lack of effect.

8.5.2 Enablers and Barriers to Effective RPE Use and Care

Table 8.1 summarizes the key enablers and barriers to effective RPE use and care from the workers' perspective. It would be worthwhile for managers to be made aware of these. Results from the management interviews illustrated that they tended to attribute RPE misuse to the worker-level, often overlooking organizational-level influences on worker behavior that represent key enabling factors (see Section 8.4.3.2). Overcoming barriers to taking action (in this case for effectively using RPE) is implicit in key health psychology theories. Managers need to provide workers with the necessary knowledge, skills, and resources to encourage compliance behavior (Rosenstock 1974, Fishbein and Ajzen 1975, Ajzen and Fishbein 1980, Ajzen 1988).

8.6 Points of Success and Points of Failure

This section brings together the findings presented in Sections 8.4 (management interviews) and 8.5 (worker observations/interviews) to summarize

TABLE 8.1

Key Enablers and Barriers to Effective RPE Use

Key Enablers	Barriers
Clear RPE policies and procedures communicated to all workers covering all stages of the RPE program (from use through maintenance)	Own judgment on RPE use and care, likely to be ineffective unless trained in all aspects of the RPE program
Disciplinary systems in place to respond to noncompliance, complimented with reward systems for good practice	No enforcement of those flouting the rules
Worker awareness that their management is committed to the RPE program	Managers "talking the talk" but not "walking the walk"
Consistent messages delivered to workers about the importance of and need for RPE use	The perception that RPE is common sense and obvious
Ongoing supervision of correct use of RPE	Inaccurate perception of risks/health effects
Seeing that managers take RPE issues seriously and quickly resolve them	Uncomfortable/poor interaction with other PPE
Getting into the habit of wearing RPE	Long periods of use at a time
Knowing someone who died/got ill through their work	Unhealthy coping styles/cognitive strategies
Worker involvement in RPE selection (early on) and fit testing for new comers	Absence of fit testing and guidance on correct storage and maintenance
Training in RPE use, storage, maintenance, and pre-use checks. Also, about the health effects of different hazards	
Refresher training	
Acceptance of responsibility for own health and safety	
Noticing immediate physical benefits	

the key points of successes and failures of RPE programs. This is achieved through comparing the performance of the best performing companies (referred to as the "proficient" group throughout this report) to those most in need of improvement (referred to as the "learners" group). These comparisons are based on (1) the key differences in RPE programs that emerged through the groupings analysis (see Section 8.3) and (2) comparisons between the two groups on each aspect of their RPE program (selection, supervision, training, etc.) following post-site evaluation. The enablers and barriers to good practice are also listed. This addresses the following objectives for this research set out in Section 8.1.2:

- *Objective 4*: By providing insights into the characteristics of the best companies compared with those most in need of improvement (the "proficient" vs. the "learners").
- *Objective 5*: By identifying the enablers and barriers to good RPE practice.

A summary of key findings is here:

- Shortfalls were evident in knowledge, awareness, and understanding, and ongoing monitoring/maintenance for both "proficient" and "learners" groups.
- Differences were found between "proficient" and "learners" at all stages of RPE programs (from selection through to maintenance).
- *Training* has obvious potential as an intervention to improve RPE program performance, although there may be other routes to progression (e.g., through RPE design).
- Differences were also noted in the level of company resources for health and safety.
- The biggest differences lie in training (quantity and quality), RPE type selected (levels of practicality and worker preference), RPE maintenance (of air supply), and the standard of occupational health provision (where implemented).

8.6.1 Key Differences: The Proficient versus the Learners

Table 8.2 lists the key differences between the "proficient" and "learners" groups on various aspects of RPE programs. Organizational resource is also included as differences were apparent for this. There were some aspects of the program where shortfalls were evident in both groups, that is, in knowledge, awareness, and understanding and ongoing monitoring and maintenance. These represent key gaps in RPE programs across industry that HSE could address through targeted communication strategies. Table 8.2 also demonstrates that different groups require different interventions. HSE's challenge lies with influencing managers in the "learners" group, that is, motivating them to go beyond a simple box ticking exercise to actively seeking advice on their RPE program and to periodically review this in line with COSHH. In addition, making these managers aware of what they need to put in place and why, overcoming their assumptions that RPE is "obvious" or "simple", This is made even more challenging by a poor economic climate in which health and safety resources may be limited.

Comparisons between the two groups on each aspect of their RPE program (up to 48 defined aspects covering selection, supervision, training, etc.) following post-site evaluation revealed notable differences in performance levels for each the following:

- Training (quantity and quality)
- RPE type selected (levels of practicality and worker preference)
- RPE maintenance (of air supply)
- The standard of occupational health provision (where implemented)

TABLE 8.2

Key Differences in RPE Programs between the "Proficient" and "Learners" Groups

Program	Learners	Proficient
Knowledge, awareness, and understanding	• Manager knowledge gaps on critical aspects of RPE programs • Manager and worker knowledge gaps on health effects and RPE generally • Managers lacked detailed understanding of HSE's respiratory guidance • Updates on RPE manufacturing developments • Shortfall in knowledge on maintenance	• Good RPE knowledge base at all levels • Good risk perception amongst managers and workers • Partial or good knowledge of HSE's respiratory guidance • Following HSE's hierarchy of controls • Seek new RPE information
Program selection	• Limited external information sources used to inform decision making • Content with achieving an "acceptable" standard (in their view), that is, being better than before or better than their competitors	• HSE/industry best practice guides decision making. • A wider external contact base used to inform selection • Proactive in searching for information/advice • Track changes through the HSE Website
RPE use	• Assume that workers know how to correctly don RPE • RPE misuse/nonuse is common and blamed on workers • Little, if any, supervision • Basic approach is to tell workers to wear RPE with little explanation as to why they should • Management failings to encourage RPE use (e.g., no fit testing when required)	• RPE standards and procedures are being followed • Managers are committed to preventing misuse • Supervision is in place at various levels to monitor and act on misuse • Developed a health and safety culture to support behavior change amongst workers • Better RPE communications in place
Training	• Poor standard of training—RPE is considered "common sense" • Little information provided to workers on RPE fit • Onus is placed on workers to find out for themselves • Senior managers sometimes unaware of what is in place • Limited information on storage/maintenance for workers • Inconsistencies in training documentation	• More likely to have well-established training systems in place • More likely to provide fit testing and refresher training • A variety of communication means used • RPE included in toolbox talks
Ongoing monitoring and maintenance	• Not yet reached this stage, still focusing on earlier stages of RPE program development • Area most in need of improvement across companies • Shortfalls in ongoing supervision and maintenance of RPE/LEV in most cases	• More likely to have ongoing supervision in place (including disciplinary) • More likely to have maintenance systems in place
Organizational resource	• Generally no in-house health and safety expertise • Limited senior management commitment • Struggling in the recession	• Evidence of in-house health and safety knowledge and expertise • Senior management commitment • Good level of resources

TABLE 8.3

Enablers and Barriers to Good RPE Practice

Enablers

Management commitment: driving through change, securing buy-in at the top, persistence, taking responsibility for health and safety (H&S)

Culture of continuous improvement: striving toward working without RPE by boosting engineering controls, and regular communications on RPE

Management knowledge pool: formal health and safety courses, supervisory (how to deliver) training courses

Assistance from other organizations: open sharing of information from sister companies and competitors

Organizational change: key triggers being a new manager responsible for health and safety, committed senior management team, and job rotation/restructuring

Noted improvements in management self-efficacy and worker satisfaction/morale through improvements made

Control availability: easy access to required controls

Legal requirement to follow tight procedures for high-risk hazards like asbestos and silica

External audits: acting on advice from HSE, insurers, and industry groups. A wake up call that workers are not fully protected

Management experience of RPE: lessons learned from experience in a previous company.

HSE support and guidance (on a personal level, good relationship with HSE inspector)

Clear RPE policies, procedures, and responsibilities in place (most likely when tight procedures are set out in legislation)

Trust established between managers and advisors (e.g., supplier representatives, health and safety consultants, occupational health providers)

Sound external advice: including clear and practical recommendations from consultants and information updates from RPE manufacturers/suppliers

Barriers

Misunderstandings and misconceptions: for example, the myth of the “28-day mask” (from manufacturers’ instructions) and need to be clean-shaven

Knowledge gaps: including the health effects of hazards, when fit testing is needed, importance of being clean-shaven, how to properly maintain RPE, importance of proper storage during breaks, and unaware of RPE manufacturing developments

Worker attitudes: particularly complacency in mature workers; “RPE invisibility”; preference for specific RPE meaning ideal type not purchased/used

RPE design: impractical for some work tasks, generally uncomfortable (hot, sweaty), perceived lack of RPE research and development in manufacturers

Time: limited time to research into RPE/sift vast amounts of information and therefore rely on recommendations from suppliers

Credit crunch/cost: limited finance to select ideal RPE and make improvements; need for low cost solutions (especially in small companies)

Perceived bureaucracy of HSE: perception that HSE is hard to please; there is never an end to the improvement needed

Respiratory disease is not considered a key industry health risk, supported by the absence of civil cases

(*Continued*)

TABLE 8.3 ***(Continued)***

Enablers and Barriers to Good RPE Practice

Management assumptions/overconfidence: that workers know about the hazards and know how to wear RPE
Desire for simple solutions: for example, selecting one type of mask for the whole workforce, simple storage, and no/limited maintenance
Absence of trigger to change: stuck in the same old ways, no independent/external review of the RPE program, relying on "being told"
Worker resistance to change
Absence of RPE being a habit: workers forget to don as they are not used to wearing RPE
Perception that company is doing better than others in industry, so why do more?
Perceived low severity of hazards: for example, complacency about general dust where silica is a risk, respiratory risks not the top priority
Interference of RPE with work processes: for example, disrupting tungsten inert gas (TIG) welding, affecting vision
Managers not "walking the talk"

8.6.2 Enablers and Barriers to Good RPE Practice

Enablers and barriers to good RPE practice are listed in Table 8.3. These have been extracted from the findings in Sections 8.4 and 8.5 and therefore represent an amalgamation of findings from the management interviews, worker interviews, and observations (including reviews of RPE documentation).

Acknowledgments

HSE's Disease Reduction Program commissioned this research. Thanks go to Len Morris, Peter Griffin, and Rob Ellis for their guidance and advice on the study. Thanks also go to Andy Weyman at Bath University, and Helen Beers and Beverley Bishop (HSE's Social Science Unit) for their help in determining the methodology and design of the research tools.

Our special thanks go to the managers and workers who took part in this research for giving generously of their time and thoughts. We hope that the report does justice to their experiences and views.

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9

Use of Respirators in an Academic Setting

Jeff Throckmorton

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9.1 Introduction

This chapter discusses respirator use in the academic environment where use conditions can be very different from in the case of general industry. There is a large body of reference material which addresses the use and selection of respirators and the various elements of an effective program. The conventional hierarchy of controls through elimination, engineering, administrative actions, and finally personal protective equipment (PPE) equally applies to the academic workplace. The academic environment presents unique challenges and differs somewhat from the industrial workplace.

The academic workplace and workforce have several attributes that must be considered when administering respiratory protection programs. First, academic environments tend to possess many low to moderate hazard stressors which arise in a decentralized manner from very diverse operations and processes. Consider the number of academic programs—instructional and research-oriented—at the undergraduate and graduate level. For each of these academic programs, research, lab-based instruction, or field activities may all possess occupational hazards that require recognition, evaluation, and control. Additionally, as research, laboratory, engineering, or other activities change over time, they tend to do so as initiated at or near the lowest level of organization—from faculty, students, or other associated researchers. This presents a complex picture of many different hazards which changes over time, and that change is generally initiated at the user level.

A second attribute to consider of the academic environment is a dynamic student workforce. The academic environment is one with a constantly changing student body that in some ways mirrors a corporate environment that must continuously train new workers as "old" workers move on following program completion. This can be challenging for health and safety programs in general, but for respiratory protection in particular because of the required training and medical examinations. Students can be viewed as workers with a short tenure and are generally a younger demographic. Both short job tenure and younger working age are positively associated with accidents and noncompliant safety behaviors (Burt, 2015).

In light of these unique characteristics, this chapter addresses the following topics:

- Program administration and how respirators are issued at the institution
- Dealing with the duration, frequency, and nature of exposures
- Addressing OSHA and a student population
- Proper respirator selection and use
- The assessment of voluntary use versus mandatory use scenarios
- Developing an effective program in a university setting

9.2 Program Administration and Respirator Issuance Considerations

One of the requirements outlined in the Occupational Safety and Health Administration (OSHA) respirator standard, 29CFR 1910.134, is that the employer establishes and maintains an effective respiratory protection program. This program should be created, overseen, and administered by a qualified and certified professional, such as a certified industrial hygienist (CIH) or certified safety professional (CSP). Indeed, OSHA specifies in 1910.134 (c) that, "the program must be administered by a suitably trained program administrator."

The university environment is dynamic and, perhaps even more than in the case of general industry, demands that the industrial hygiene (IH) or safety professional utilize proactive business practices that enable awareness of all operations. This kind of IH or safety professional must also be able to evaluate academic operations, whether related to research or general operations, prior to the time that staff, faculty, or students are exposed. Of course, awareness of the general OSHA requirements set forth in 1910.134 must be remembered, but the diverse nature of the academic environment expands the argument and issues.

Typically, a program is coordinated through one department or group, but in some cases a university will have professionals from various working groups administer a program independently. In such cases, it is critical that communication and coordination exist between the groups to ensure uniform program administration. Some general considerations in an academic setting include:

- If more than one group issues respirators, how will different departments run separate programs? In such cases, it is recommended that there be close and effective communication between those groups, if for no other reason than to assure that implementation policies are the same across the entire institution.
- How are issued respirators paid for? Are they free to users? If an inventory is maintained, who will maintain it? How will users pick up masks? Are individual departments to be charged back for the respirators (either voluntary of mandatory) that they use?
- Who will pay for cartridges when they need to be replaced under the change out schedule?
- Who has the responsibility to notify individuals of the initial and annual fit tests, and follow through to make sure that it happens? Likewise for the initial and follow up medical evaluations?

Regarding medical evaluation, 1910.134(e)(1) the standard states, "the employer shall provide a medical evaluation to determine the employee's ability to use a respirator before the employee is fit tested or required to use the respirator in the workplace." Although fit testing is required annually, medical evaluation is not required annually unless a condition or change arises such that re-evaluation is warranted.

Institutions have legacy systems and arrangements which dictate how the preceding issues are addressed. But as organizational variations are considered, an argument can be made that the best program control and protection comes from a completely centralized system, where respirators are paid for by a single department, with all aspects of the program organized and run by a single office or department.

In the case of one institution, the IH group allowed the warehouse to stock and carry N95 type masks, generally for use by the facilities group, while at the same time maintaining a stock of respirators at the safety office. Although this was an easy way for facilities personnel to quickly obtain N95 respirators, it also provided a pathway whereby it was possible to easily misuse them because the safety group was neither in control nor, for that matter, even aware of the use conditions. This institution later changed the policy so that all respirator issuance was controlled by the safety office, requiring direct contact between safety professionals and the end users. This change allowed much greater awareness on the part of the safety professionals of what work personnel were engaged in, allowing greater control and protection for those workers.

Regarding payment for respirators, this same institution made the decision that the safety department would pay for all respirators, regardless of type, campus wide. Although this required a budget adjustment for the safety group, it was believed that the higher level of control and care was worth the cost, coupled with the belief that if respirators were available without charge to the end users, any financial excuse for not using them was removed, encouraging more widespread uses especially in the case of N95 (filtering facepiece) type masks.

9.3 Duration, Frequency, and Concentration of Exposures

It can be a challenge to evaluate the duration, frequency, and contaminant concentration from exposures within a university environment. This can be particularly problematic with students where exposures are typically variable, irregular, and often last no longer than an hour or two. In the case of an exposure based on an 8-hr time-weighted average (TWA) and for a compound which has neither a short-term exposure limit (STEL) or ceiling limit, it may be tempting to ignore or overlook monitoring due to the brevity of exposure. The reader is reminded of the excursion limit guidelines and advice set forth by the American Conference of Governmental Industrial Hygienists (ACGIH). The excursion limit guidance from ACGIH is reproduced below.

> For many substances with a [threshold limit value-time weighted average] TLV-TWA, there is no TLV-STEL. Nevertheless, excursions above the TLV-TWA should be controlled, even were the 8-hr TLV-TWA is within recommended limits. Excursion limits apply to those TLV-TWAs that do not have TLV-STELs.
>
> Excursions in worker exposure levels may exceed three times the TLV-TWA for no more than a total of 30 minutes during a workday, and under no circumstances should they exceed five times the TLV-TWA, provided that the TLV-TWA is not exceeded.

Although an operation may be brief, the author has witnessed very high levels of contaminants being generated during short operating periods. This has sometimes been linked to the fact that proper controls were not established under the assumption that overexposure was not possible during a short process, or that it was so brief that it essentially did not matter.

9.4 Addressing OSHA and a Student Population

It is true that OSHA provisions pertain only to employees. Of course, the definition of an "employee" can be extended to students in many situations such as when students receive any form of remuneration for their work. Nevertheless, there is both a moral and legal imperative to protect all individuals who are at risk. The legal, reputational, and financial threat to any institution which would allow harm to any student is clear. Although the OSHA standards may not technically apply in the case of students who are not employees, the protection of all students should be addressed in the respiratory protection program. For the purposes of this document, all students will be considered as falling under the same protective requirements as "ordinary" employees.

In 1910.134(k), OSHA specifies that the employer "provide effective training to employees who are required to use respirators. The training must be comprehensive, understandable, and recur annually, and more often if necessary. This paragraph also requires the employer to provide the basic information on respirators in Appendix D of this section to employees who wear respirators when not required by this section or by the employer to do so." This requirement sets forth the question of what is the most effective way to conduct training in an academic environment where users are constantly changing in their exposures and schedule. One effective approach is through close communication both with faculty and managers who employ students and ultimately have the responsibility to assure that their students and personnel are adequately protected before any exposure is permitted. This approach can be used for situations where training is presented electronically or by personal lecture and demonstration, and allows for the level of training to vary depending upon the nature of the situation. A key to this approach is assuring that all departments know of the requirements for respirator training, especially in the case of new managers or faculty members. This awareness can be facilitated by coordination with an academic safety committee or equivalent.

It is perhaps slightly easier in the case of facilities and maintenance personnel where employees are hired by a specific department. An effective way to train facility staff can be through the use of "circuit training" where each department is scheduled for an annual refresher conducted by the safety/IH group. Records must be kept of the training to comply with OSHA requirements. However, in a system of scheduled "circuit training," provision must be made to train new hires in the proper use of respirators as soon as they are hired, rather than waiting for the scheduled date of the annual training.

9.5 Proper Respirator Selection and Use

There are several documents which address steps to proper respirator selection and use. It is critical that only qualified individuals make the evaluation and final decision as to what type of protection is needed in each situation. Elements which should be considered for respirator selections include:

- The nature of the process or operation
- Types of respiratory hazards
- Possibility of oxygen deficiency
- Location of the hazardous atmosphere
- Duration of respirator use
- Worker activities
- Respirator characteristics
- Respiratory protection factors (see table in 1910.134(d)(3)(i)(A))
- Regulatory requirements

Respirators may be:

- Tight-fitting—that is, half masks, which cover the mouth and nose and full facepieces that cover the face from the hairline to below the chin; or
- Loose-fitting, such as hoods or helmets that cover the head completely.
- In addition, there are two major classes of respirators:
  - Air purifying, which remove contaminants from the air; and
  - Atmosphere supplying, which provide clean, breathable air from an uncontaminated source. As a general rule, atmosphere-supplying respirators are used for more hazardous exposures.

Individuals typically do not always think of academic settings as locations where oxygen deficient situations exist. Two common locations where oxygen deficient situations can exist include mechanical rooms with chillers and those associated with confined space entry. Looking at the former, it is not uncommon for chillers to be located in basement rooms, in some cases in rooms with little or no ventilation. Chillers operate using chlorofluorohydrocarbon gases which are heavier than air and can settle in an enclosed space presenting a significant asphyxiation hazard in the event of a release. Some institutions have addressed this hazard by installing alarms in some mechanical spaces and making emergency escape hoods, which provide several minutes of breathing air, immediately accessible for use to safely exit from an area. Of course, such escape devices must be inspected monthly per 1910.134. The reader should note that if a campus is depending upon an internal rescue team to support confined space entry, any individual expected to respond must have the proper respirators suitable for emergency entry and they must be maintained on an emergency use basis.

It is also important to recognize some of the chemicals for which air-purifying respirators (APRs) are not suitable. Although critical for all users, it is particularly important for academic users to understand this limitation as in some cases a "one size fits all" belief may be encountered, especially in cases where a wide variety of chemicals may be encountered. APRs are *not* suitable for atmospheres containing:

- Acrolein
- Aniline
- Arsine
- Boron hydrides
- Bromine
- Carbon dioxide
- Carbon monoxide
- Carbonyls
- Carbon disulfide
- Cyanogen
- Dimethylaniline
- Dimethyl sulfate
- Fluorine
- Hydrogen cyanide
- Hydrogen fluoride
- Hydrogen selenide
- Hydrogen sulfide
- Isocyanates
- Methanol methyl bromide
- Methyl chloride
- Methyl iodine

- Nickel carbonyl
- Ozone
- Phosgene
- Phosphine
- Phosphorus trichloride
- Stibine
- Sulfur chloride
- Vinyl chloride

9.6 Assessment of Voluntary Use versus Mandatory Use Scenarios

A successful respirator program must specify whether respirators may be used on a "voluntary" basis. Key differences between mandatory and nonmandatory use include the requirements which apply to fit testing, medical evaluation, and fitness determination, annual training, respirator cleaning, and program evaluation.

Although technically respirator use on a "nonmandatory" basis can occur with little or no oversight, for a program to have control and program integrity it is recommended that nonmandatory use only take place or be allowed after careful evaluation of the work operation from the onsite CIH, CSP, or another qualified professional. In this fashion the professional can investigate and verify that the use on a "nonmandatory" basis is appropriate. If there is no review or oversight, it is possible that "mission creep" will occur in the use of respirators where a user will assume that what is appropriate in one situation is also appropriate in another different situation. This also assures that users will be informed of the OSHA requirements for voluntary use which are outlined in Appendix D of 1910.134.

One successful approach addresses the method by which respirators are issued. In one model, the decision as to what type of respirator is needed, as well as the issuance of the respirator, is solely controlled by the IH group. To obtain any type of respirator, a user must first complete a form which provides the name of the supervisor or principal investigator as well as an explanation of the materials involved and nature of the operation. This form is singed by both the user and the supervisor and is then directed to the IH group who can either approve with the information provided or make a more thorough investigation of the situation. Once the industrial hygienist has determined the nature of the hazard and type of respiratory protection needed, he can approve, reject, or modify the request. In some cases, this may require the industrial hygienist to conduct sampling.

A database should be kept of each person who is issued a respirator along with pertinent details as to the respirator type and model number, supervisor and hazards and, in the case of mandatory usage, the date of fit testing and medical evaluation. Such a system also enables the program administrator to locate users quickly and easily which can be beneficial in the case of, for example, a supplier of a respirator issuing a recall.

This approach has also proven to be valuable in helping to locate operations and conditions which were previously unknown to the IH group. By the supervisor signing, the supervisor assumes responsibility for the respirator users in his group and helps provide input as to the effectiveness of the program.

Some institutions have found that for some applications the use of filtering facepieces on a voluntary use basis is practical. Of course, this occurs only after an industrial hygienist has made a careful assessment of exposure conditions and verified that exposures above any standard, or in excess of the excursion limits, are not realistically possible and that voluntary use is acceptable.

This also touches on a discussion as to how much the voluntary use of respirators should be encouraged. As long as an understanding of the use limitations is clearly explained, one direction of thought is to encourage their use whenever there is the possibility of exposure, especially for what might be termed "nuisance dust" such as during any construction demolition work. Practicing industrial hygienists may seek to protect people from inhaling hazardous and potentially harmful dusts and agents to the extent practical, regardless of whether exposures may be below the permissible exposure limit (PEL) or TLV. Since historical IH standards tend to become more conservative, it would seem to be wise to encourage the general use of filtering facepieces. OSHA issued a letter of interpretation providing useful additional information on the voluntary use of filtering facepiece respirators (OSHA 2006). Key points of this letter include

- Voluntary use of respirators in nonhazardous atmospheres do not require the mask to be fit tested, so the standard does not prohibit facial hair.
- In nonhazardous atmospheres, employers are not required to ensure workers wear respirators according to manufacturers' instructions.
- If an industrial hygienist *requires* a respirator to be worn in a particular area, even if the airborne contaminants are below the PEL, the respirator use is *not* considered voluntary.
- If an industrial hygienist *allows* the voluntary use of a respirator and the airborne contaminants are below the PEL, the respirator use is considered voluntary.
- The respiratory protection standard considers the terms "filtering facepieces" and "dust masks" to be synonymous.

9.7 Further OSHA Considerations

In 1910.134 (c), OSHA provides a list of program elements which must be addressed in a respirator program, be it an academic or general industry setting. Following is a list of those items taken from the standard:

- **1910.134(c)(1)(i)** Procedures for selecting respirators for use in the workplace
  - It is recommended that a university program be set up so that only qualified professionals are allowed to determine what respirators are appropriate for use situations. It is important that the safety/IH group maintain control over what is allowed to come onto campus.
- **1910.134(c)(1)(ii)** Medical evaluations of employees required to use respirators
  - The OSHA regulation is clear as to what is required as part of the medical examination. A university needs to consider if the evaluation will be contracted out or conducted by an internal medical facility.
- **1910.134(c)(1)(iii)** Fit testing procedures for tight-fitting respirators
  - Fit testing procedures are addressed in detail in this section. Again, the university needs to determine if they will use internal personnel to conduct fit tests or if the task will be contracted to an external facility.
- **1910.134(c)(1)(iv)** Procedures for proper use of respirators in routine and reasonably foreseeable emergency situations
  - The university has to determine what personnel may be involved in both the routine and emergency use of respirators. In some cases, for situations other than emergency escape, universities may have agreements with local emergency response providers for support and not develop internal rescue or response capability. Such arrangements should be carefully examined and vetted ahead of time.
- **1910.134(c)(1)(v)** Procedures and schedules for cleaning, disinfecting, storing, inspecting, repairing, discarding, and otherwise maintaining respirators
  - Individuals who are issued respirators must be provided with clear directions for proper respirator inspection, care, and use.
- **1910.134(c)(1)(vi)** Procedures to ensure adequate air quality, quantity, and flow of breathing air for atmosphere-supplying respirators

  - In cases where breathing air is supplied, a clear understanding has to be established as to how these issues are addressed. This can be critical in a situation where student employees who may not have had proper training are involved. For example, a student might not have thought through the implications of improper placement of a breathing air compressor away from sources of contamination.
- **1910.134(c)(1)(vii)** Training of employees in the respiratory hazards to which they are potentially exposed during routine and emergency situations
  - Documentation of proper training in a rapidly changing population is critical. Training is to be repeated annually.
- **1910.134(c)(1)(viii)** Training of employees in the proper use of respirators, including putting on and removing them, any limitations on their use, and their maintenance
  - Since a majority of students may have never had experience with a respirator, it is critical that sufficient time and detail be allotted in training to demonstrate the proper donning and doffing of a respirator, as well as the use limitations. Particular attention must also be given to students who use English as a second language to assure that they understand the principles being taught.
- **1910.134(c)(1)(ix)** Procedures for regularly evaluating the effectiveness of the program
  - Attentive, informed, and engaged supervisors, managers, and principal investigators are critical to truly assessing the success and effectiveness of a program. The IH/safety personnel should interface with them as necessary and obtain their support in helping to assess program effectiveness.

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10

Social Marketing Campaign Promoting the Use of Respiratory Protection Devices among Farmers

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Risto Rautiaiuen, and Debra J. Romberger

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10.1 Introduction

This chapter describes the use of marketing concepts in a systematic approach to influence voluntary respiratory protective device (RPD) use among farmers. The social marketing planning process for the project incorporated six key decision points, each informed by formative research or health behavior theory (Figure 10.1 and Table 10.1).

Social marketing has been described as "seek[ing] to develop and integrate marketing concepts with other approaches to influence behaviors that benefit individuals and communities for the greater social good," (International Social Marketing Association, 2013) and as a systematic approach with a focus on voluntary behavior (Andreasen 1994). Social marketing has been shown to be effective in agriculture-related prevention programs (Chapman et al. 2004, French et al. 2011, Parrott et al. 1998, Sorensen 2010, 2011). The six step logic model (Figure 10.1) used to guide the planning process for this project aligns

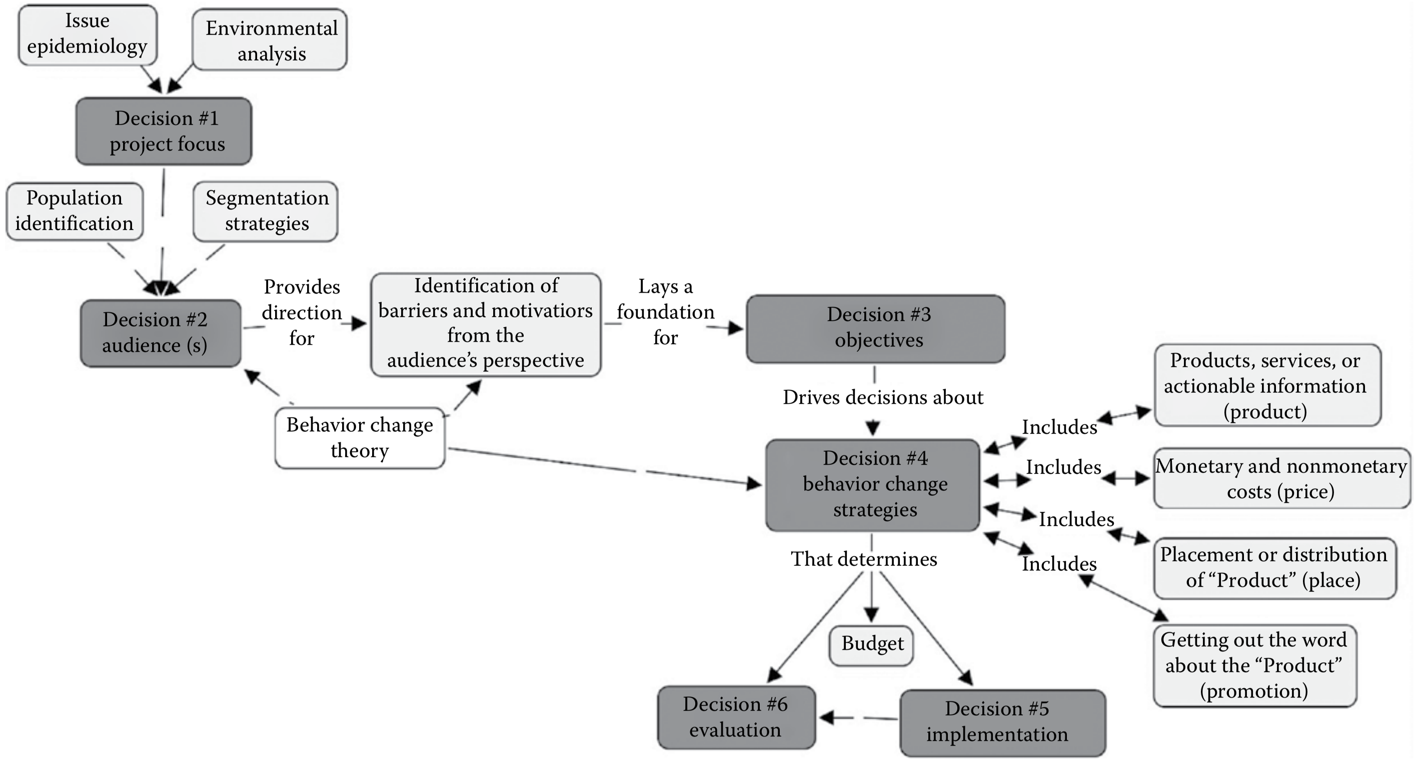
Issue epidemiology
Environmental analysis
Decision #1 project focus
Population identification
Segmentation strategies
Decision #2 audience (s)
Provides direction for
Identification of barriers and motivatiors from the audience's perspective
Lays a foundation for
Decision #3 objectives
Behavior change theory
Drives decisions about
Decision #4 behavior change strategies
Includes
Includes
Includes
Includes
Products, services, or actionable information (product)
Monetary and nonmonetary costs (price)
Placement or distribution of "Product" (place)
Getting out the word about the "Product" (promotion)
That determines
Budget
Decision #6 evaluation
Decision #5 implementation

FIGURE 10.1
Decision points in the social marketing planning process with key inputs.

TABLE 10.1

Key Decision or Action Points in the Planning Process with Formative Research or Health Behavior Theory Inputs

Key Decision or Action Points	Informed by
Project focus	Formative research (issue and environmental analysis)
Audience(s)	Population identification, segmentation strategies, and health behavior change theory
Objectives	Formative research (barriers and motivators relevant to the target behavior) and health behavior theory
Behavior change strategies	Objectives and health behavior theory
Implementation	Budget and health behavior theories
Evaluation	Objectives, implementation, and budget

with essential aspects of the social marketing process (Table 10.2, Lefebvre and Flora 1988) commonly accepted by social marketing professionals, including consumer orientation, formative research, and use of the marketing mix.

Agricultural workers have among the highest rates of nonfatal occupational injuries and illness in the United States (NIOSH 2014). Respiratory illnesses are among the most common ailments seen in agricultural workers (NIOSH 2014), ranging from upper respiratory symptoms to chronic obstructive pulmonary disease and exacerbation of underlying diseases such as asthma (Eduard et al. 2009, Von Essen and McCurdy 1998). Proper RPD use is a primary prevention strategy to reduce agricultural workers' risk of respiratory illness (Donham 2007, Kusaka 1993, Linaker and Smedley 2002, Von Essen and McCurdy 1998). Training in the proper use of personal protective equipment (PPE), such as RPDs, has also been shown to be effective in increasing RPD use as an injury and illness prevention strategy (Day 2009, Donham 2011, Jenkins 2007, Kim 2012).

The Central States Center for Agricultural Safety and Health (CS-CASH) is a National Institute of Occupational Safety and Health (NIOSH) agricultural

TABLE 10.2

Eight Essential Aspects of the Social Marketing Process

1. Consumer orientation to realize organizational goals
2. Emphasis on voluntary exchanges of goods and services between providers and consumers
3. Research in audience analysis and segmentation strategies
4. The use of formative research in product or message design and the pretesting of these materials
5. Analysis of distribution (or communication) channels
6. Use of the "marketing mix"—that is, utilizing and blending product, price, place, and promotion characteristics in intervention planning and implementation
7. A process tracking system with both integrative and control functions
8. A management process that involves problem analysis, planning, implementation, and feedback functions

safety and health center based in Nebraska and serving a seven-state region. As part of its outreach programs, CS-CASH used a systematic social marketing planning process to influence the use of respiratory protection among farm workers in its region. The six key decision points reflect commonly agreed upon principles of social marketing (Kotler and Lee 2011, Lefebvre and Flora 1988).

10.2 Decision 1: Project Focus

Determining the focus of this social marketing-based project began by reviewing two key inputs: (1) frequency, distribution, and causes of respiratory disease in farm workers (issue epidemiology); and (2) an analysis of the various environmental factors that impact or influence the issue of interest including economic, demographic, and cultural forces. The project team included a physician with extensive experience treating pulmonary disease resulting from agriculture-related exposures and two public health practitioners with extensive experience working with farmers and others in the agricultural industry on research and prevention programs. These team members served as an expert review panel throughout the planning process. A literature review of current data on respiratory illness among agricultural workers augmented the review panel's expertise. The literature review revealed significant risk of respiratory-related illness, significant costs associated with farm workers' injuries, and successful mitigation of risk and cost through training (BLS 2012, Donham 2007, Leigh et al. 2011, Linaker and Smedley 2002).

Problem analysis in the form of input from the expert review panel and findings from the literature review led to the decision to focus the project on increasing agricultural workers' knowledge about and use of RPD. Consistent, correct use of RPDs is an effective way to reduce the risk of respiratory illness resulting from agriculture-related exposures (Donham 2007). Many agricultural workers employed on family farms or small operations that are exempt from regulations regarding RPD use either do not wear masks, wear them inconsistently, or do not wear them properly (MacFarlane 2008, Mitchell and Schenker 2008).

10.3 Decision 2: Audience(s)

Decisions about the focal audience or audiences for a social marketing-based project involve key inputs of identifying a specific population and developing audience segmentation strategies. Although the general population of farmers appeared to be the obvious audience for this project, planners recognized the importance of establishing an initial picture of the potential audience before developing a segmentation strategy. Formative research revealed that farmers in general tend to think that the symptoms of respiratory illness they experience are normal because such symptoms are prevalent among farm workers. In the United States there is also a cultural perspective in which farm workers see themselves as strong and invincible and tend to believe they are immune from the more severe consequences of exposure. Farm workers may not see respiratory illness associated with exposure in these settings as a major health problem and may also believe that respirators are uncomfortable to wear.

Attitudes and beliefs related to cost and convenience also exist. Farm workers may not know which type of respirator they need and, if expert help is not available at the point of purchase, may avoid making the purchase because they don't want to spend money on the wrong type of respirator. They may see respiratory protection as an extra expense, or they may not know where to purchase respirators. Respiratory equipment may not be stored in a convenient location near the point of use. There may also be perceptions that maintaining and putting on the respirator take too much time.

After reviewing the formative research relative to farm workers and respiratory protection use in general, the planning team identified four audiences for the campaign:

1. Corn and soybean farmers
2. Non-regulated confined animal facility workers
3. Commercial pesticide applicators
4. Farm supply store personnel

Corn and soybean farmers and non-regulated confined animal facility workers were identified because the contaminants these two groups are exposed to lead to increased risk of developing respiratory disease. These workers are typically engaged in small operations that are not subject to Occupational Safety and Health Administration (OSHA) regulations regarding RPD use.

Commercial pesticide applicators were identified because the formative research revealed that even though these workers are trained on appropriate RPD use, once in the field they often forego its use or use it improperly, increasing their risks of developing respiratory disease.

Farm supply store personnel were identified because formative research revealed that the sales staff at farm supply stores, where agricultural workers and commercial pesticide applicators are most likely to purchase RPDs, lack the education necessary to advise farm workers in RPD selection and use. This group had the potential for a high impact in supporting behavior change among the at-risk groups. However, developing behavior change strategies for farm supply store personnel would have required including members of the entire supply chain involved in distributing RPDs to the major farm supply outlets in the CS-CASH region. The scope of the work required to reach this audience went well beyond the resources and capabilities available for this project, so farm supply store personnel were eliminated as an audience.

During the discussion of behavior change strategies, the project team concluded that the strategies needed to reach agricultural workers and commercial pesticide applicators would be different. Therefore, the project team decided that focusing on corn and soybean farmers and non-regulated confined animal facility workers with no training in the use of RPD would be the most efficient use of project resources and have the greatest potential impact on changing behaviors.

10.4 Decision 3: Objectives

Once the potential audience had been refined and segmented, a literature review relative to the identified audience was conducted to identify barriers and motivators that would inform decisions about behavior, knowledge, and belief objectives. Identification of barriers and motivators from the audience's perspective is a key input into determining objectives. Some social marketers prefer to conduct this type of formative research before identifying audience segmentation strategies. Making sure barriers and motivators are identified from the point of view of the audience's perspective is key, regardless of whether this step is done before or after identifying audience segmentation strategies. The audience perspective can be gained either through a concentrated review of the literature or through discussions with key informants or members of the target audience. It is imperative that planners not assume they know what those barriers and motivators are regardless of how well-versed they may be with the issue being addressed.

A concentrated literature review provided an understanding of barriers and motivators from the audiences' perspective which was confirmed by the expert review panel. Barriers to RPD use were identified by examining factors associated with negative perceptions of RPD use, including difficulty in communicating, breathing through the mask, and nasal stuffiness (Fukakusa 2011, Kirkhorn and Garry 2000). Other barriers included concerns about the costs of purchasing masks (Kirkhorn and Garry 2000). In addition, wearing a mask for an extended period of time can be uncomfortable because it tends to become hot and moist from the wearer's breath and can cause moisture to form on glasses or protective eye gear.

Safety knowledge and concern about respiratory illness motivate RPD use, with higher levels of knowledge correlated with greater use (Day 2009, MacFarlane 2008, Mitchell and Schenker 2008, Reed 2006) and lower probability of injury (Beseler and Stallones 2010, Day 2009). Younger age, nonsmoker, and having respiratory or skin problems were traits all positively associated with RPD use (MacFarlane 2008, Syamlal 2013). Convenient access to RPD, safety training, fit testing, and compliance of coworkers are also positively associated with RPD use (Carpenter 2002). Factors associated with positive perceptions of RPD use include reduced chance of respiratory impacts such as wheezing, nasal congestion, and lung damage (Schenker et al. 2002). Other factors shown to influence RPD use include convenience of storage location, concerns of family members, and prompts such as warning labels or stickers (Carpenter 2002). Those who are aware of risks or have health concerns are more likely to see RPD use as a benefit (Carpenter 2002, MacFarlane 2008).

The greatest perceived barriers were selection of masks, fit of masks, difficulty in storing masks appropriately near where they are needed, and lack of knowledge about appropriate masks for different environments. The greatest perceived benefits were reduced wheezing and nasal congestion.

Social marketing campaigns include three types of objectives: belief objectives, knowledge objectives, and behavior objectives (Kotler and Lee 2011). Formative research revealed a lack of knowledge among farm workers about the risk of long-term exposure and negative beliefs about the effectiveness of preventive measures. This information drove the development of objectives for this campaign. The overall goals for this campaign were

- Corn and soybean farmers will correctly use NIOSH-approved N95 disposable respirators during harvest in dusty environments.
- Non-regulated confined animal facility owners and workers will correctly use NIOSH-approved N95 disposable respirators during the dustiest activities.

Belief objectives are identified as beliefs that need to be fostered in order to help motivate audience members to perform the desired behavior (Kotler and Lee 2011). Formative research revealed perceived barriers associated with using RPDs correctly and perceived benefits of better respiratory health, led to the following belief objective for this campaign:

- Audience members will believe that using a NIOSH-approved N95 disposable respirator in identified settings will make a difference in their short- and long-term health by preventing respiratory illness.

Knowledge objectives are identified as the knowledge needed to assist an audience in performing the desired behavior (Kotler and Lee 2011). Formative research revealed that the target audiences are not well informed about when to wear RPDs, correct types of RPDs, and fit and storage of RPDs. Therefore, the following knowledge objectives were identified for this campaign:

- Audience members will know what constitutes a NIOSH-approved N95 respirator.
- Audience members will know what constitutes a dusty environment in which the respirator should be used.

- Audience members will know how to identify correct fit of respirator.
- Audience members will know how to correctly choose store respirators.

Behavior objectives are identified as the desired change in behavior and are articulated as specific, measurable outcomes (Kotler and Lee 2011). Based on the perceived benefit that using RPD reduces the risk of respiratory illness, the following behavior objectives were identified for this campaign:

- Ten percent of corn and soybean farmers exposed to this campaign will report wearing NIOSH-approved N95 disposable respirators during harvest in dusty environments.
- Ten percent of owners and workers in non-regulated confined animal facilities exposed to this campaign will report wearing NIOSH-approved N95 disposable respirators during the dustiest activities.

10.5 Decision 4: Behavior Change Strategies

In a social marketing-based project, behavior change theories and models are used at several points in the planning process to guide decision making. Constructs of the theories or models chosen influence decisions about the audience, objectives, and behavior change strategies. Using the Transtheoretical Model (Stages of Change) this campaign focused on audience members in the contemplation and preparation stages. Those in the contemplation stage are considering adopting the desired behavior of using RPDs consistently and correctly within the next 6 months (Prochaska and Velicer 1997). Audience members in the preparation stage are considering engaging in the desired behavior of using RPDs consistently and correctly within the next 30 days (Prochaska and Velicer, 1997).

This campaign used the 4P model (product, price, place, and promotion) to identify the behavior change strategies to be used in achieving the identified objectives. In social marketing these behavior change strategies are often referred to as the marketing mix. Products can include tangible items, intangible services, or actionable information that enables the audience to engage in the desired behavior. Actionable information is different from promotional communications in that it gives the audience specific instructions in how to engage in the desired behavior. The product component of the behavior change strategies for this campaign consisted of actionable information and a brightly colored storage bag. The actionable information was designed to increase audience members' self-efficacy in using RPD by giving them specific instructions on how to identify the correct RPD to use in different exposure situations, appropriate situations when RPDs should be used, and appropriate fit and storage of RPDs.

Four videos were developed using a Southwest Iowa farm couple and a representative of the AgriSafe Network, a national nonprofit membership organization that provides training and technical assistance in addressing the health and safety of farm families. Formative research revealed a preference for videos as a method of receiving PPE training (Carpenter 2002). The video content used a conversational style with the AgriSafe representative engaging the farm couple in a discussion about and demonstration of RPDs. The information was divided into four videos of approximately 3 minutes each, to enable viewers to access the content of interest without having to view an entire video. The videos addressed the belief and knowledge objectives of this campaign through four topics: understanding the risks of exposure, choosing the right mask, getting the right fit, and proper care of masks.

Because storage of RPDs was identified in the formative research as a barrier to RPD use, a bright orange storage bag with the message "Smart Farmers Wear Masks" was also developed as part of the product strategy. The bag makes it possible to store RPDs in a manner that keeps the mask clean and makes it easily accessible at the point where the wearer will engage in the desired behavior. The "Smart Farmers Wear Masks" tag line and a graphic of a mask on the bag serve as prompts of the desired behavior. The bag is consistent with the strategy of making the product available close to the time and place where the audience will engage in or be thinking about the desired behavior (Kotler and Lee 2011). Messaging used on the bag is also consistent with the formative research that identified the use of prompts to influence mask usage (Carpenter 2002). The orange storage bag filled with a sample mask and hearing protection has become a staple of the "give away" items distributed during CS-CASH outreach events including farm shows, county fairs, educational sessions, and agriculture-related conference exhibits.

The price "P" of the 4P model involves monetary and nonmonetary costs associated with adopting the desired behavior. The monetary costs associated with adopting the desired behavior were limited to the cost of the RPDs and nominal costs of transportation to purchase the devices. Addressing monetary costs of the behavior change was beyond the scope of this campaign. Nonmonetary costs included the inconvenience associated with RPD use and the physical discomfort associated with wearing a mask that covers the mouth and nose. Information provided in the instructional videos addressed the physical discomfort of wearing RPDs by providing advice on how to choose and wear a mask, including obtaining a correct fit to minimize discomfort. The instructional videos also demonstrated how to correctly put on (don) and remove (doff) a mask.

The place "P" of the 4P model involves placement or distribution of the product. The instructional videos were placed on YouTube with links provided on the CS-CASH website. The RPD storage bags were distributed at farm shows across the CS-CASH region during fall 2012 and spring 2013. Information about accessing the instructional videos was distributed at the farm shows. Members of the CS-CASH outreach team also used interactions with farmers at farm show exhibits to demonstrate correct mask fit and correct donning and doffing, and to discuss the risks associated with not using RPD.

The promotion "P" of the 4P model involves promoting the product and includes key messages to promote desired behavior. Based on formative research, two message concepts were developed. One dealt with the agricultural community's core value of the importance of family and emphasized the importance of using RPD for the sake of the family. Using an emotional appeal, the tagline for this message read, "Save your breath for the important times in life." The second message adopted a more factual approach and included the tagline, "Keep what you can and can't see out of your lungs." Both message concepts included a list of potential respiratory consequences of not wearing RPDs.

Both message concepts were pretested through intercept interviews conducted during Husker Harvest Days, the largest farm show in Nebraska. Approximately 100 members of the agricultural community interacting with staff at the CS-CASH exhibit were shown copies of each message to assess which message would have a greater impact. The fact-based message, "Keep what you can and can't see out of your lungs," was judged to resonate more widely with farmers and to be more memorable that the emotional appeal. In addition, intercept interview respondents indicated that they were likely to open an email from CS-CASH and click on the video link. They also indicated that they usually or sometimes wore a mask in dusty conditions.

Promotional strategies included print and electronic distribution of informational materials and videos. Print materials and the RPD storage bags were distributed at farm shows and other venues. Printed flyers included a URL to access the instructional videos. Electronic materials included quarterly email campaigns of key messages and links to the instructional videos. The CS-CASH website also provided a distribution channel for both the instructional videos and electronic versions of the print materials.

The marketing mix met the belief objective by providing information about the benefits of using RPDs delivered by credible spokespersons. The video content addressed the knowledge objectives by providing an engaging, convenient format for learning about types of RPDs, when to wear RPDs, how to wear RPDs correctly, and how to care for RPDs.

10.6 Decision 5: Implementation

Budget considerations and the timing of the project influenced implementation. Planning began in spring 2012 with the goal of launching the campaign before fall harvest. This campaign was launched in August of 2012. The implementation strategy relied primarily on electronic communication because it is a relatively low-cost way of reaching large numbers of the audience. The instructional videos were posted to the CS-CASH YouTube channel in November 2012 and subsequently added to a YouTube channel featuring work by all of the NIOSH-funded U.S. Agricultural Safety and Health Centers. Subsequent evaluation reinforced the effectiveness of this strategy. Implementation also relied on one-on-one communication between CS-CASH staff and audience members at farm shows across the CS-CASH region.

For the first email campaign, CS-CASH partnered with Farm Market ID, an agri-marketing firm, which provided farm and agribusiness email addresses. The first message was sent using the Farm Market ID brand. However in order to maintain control of the CS-CASH brand, subsequent messages using the CS-CASH brand were sent to approximately 16,000 email addresses using a bulk email subscription service.

Exhibits at farm shows across the CS-CASH region were also a key distribution strategy because CS-CASH outreach staff had the opportunity to further engage agricultural workers in demonstrations of RPD selection and fit.

10.7 Decision 6: Evaluation

Process evaluation measures were used to assess implementation of the campaign which ran from August 2012 to September 2013. The videos received varying numbers of views, which could indicate which aspects of RPDs agricultural workers find most problematic (Table 10.3). The video on how to get the right RPD fit received the most views, with 1695 views in the first year of the campaign and continues to receive the most views with just under 5000 views received as of July 2016. This is consistent with the findings of the formative research that showed proper fit is a primary concern.

The mass email distribution list grew from 14,168 for the initial email to more than 16,000 for subsequent mailings. Statistics on the email campaign show a top open rate of approximately 10% and a click-through rate of approximately 1.2% during the course of the campaign which were lower than the industry average (Email Marketing Benchmarks: Average Email Campaign Stats by Industry, 2014). Open and click-through rates varied with

TABLE 10.3

You Tube Video Analytics for four CS-CASH Videos on RPD

Video Topic	**Cumulative # Views (November 2013)**	**Cumulative # Views (as of July 2016)**
How to get the right fit	1695	4555
Choosing the right mask	486	1565
How to properly care for your mask	427	1147
Understanding the risks	296	1071

FIGURE 10.2
RPD storage bags worn at farm show.

message content with exposure warning messages receiving higher rates. During the course of the campaign, CS-CASH outreach staff attended 15 multi-day farm shows in the CS-CASH region and interacted with approximately 5000 members of the agricultural community, distributing over 3000 RPD storage bags and print materials. The storage bags received such positive reception that the concept has been repurposed for other CS-CASH outreach initiatives including a hearing protection project (Figure 10.2).

Outcome evaluation was conducted at the close of the campaign via electronic survey emailed to 1677 email addresses of recipients who received the campaign's email messages and opened them, approximately 10% of the mail list. The evaluation response rate was low; however, the survey provided valuable insights into the performance of the campaign. Survey respondents indicated that the information they received on the use of RPDs increased their knowledge about the health risks of dust exposure (72.7%) and increased the likelihood that they would wear a mask in dusty conditions (63.6%). However, only 40% of survey respondents indicated that the educational emails changed the frequency with which they wore a mask in dusty conditions. Since the evaluation response rate was less than 10% of the audience that received the email messages, it was not possible to determine if the objectives established for this campaign were met. In addition, evaluation did not identify respondents by the type of exposure they encounter. Nonetheless, the survey results indicate that the campaign had a positive impact on knowledge and use of RPDs.

10.8 Alignment of Essential Aspects and Planning Process

The social marketing-based planning process (Figure 10.1) for this project aligns with the eight essential aspects of the social marketing process (Table 10.2) in several ways. Essential Aspect 1, consumer orientation to realize organizational goals, was addressed through the planners' decisions about audiences (Decision 2), behavior change strategies (Decision 4), and implementation (Decision 5). The planners used segmentation strategies to reach the audience that represented the greatest opportunity for impact. Behavior change strategies took into consideration the audiences' preferences for communication channels as well as providing products that would support their behavior change efforts. Implementation of the project also took into account consumers preferred communication channels. All of these decisions support CS-CASH's organizational goal of developing, implementing, and evaluating prevention strategies that improve health and safety within the agricultural community.

Essential Aspect 2, emphasis on voluntary exchanges of goods and services between providers and consumers, has come under scrutiny in recent years. Some social marketers interpret this exchange in terms of providing incentives to those that engage in a desired behavior change (Kotler and Lee 2011) while others argue that the idea of exchange is less clear. In the case of this project the concept of voluntary exchange was addressed through development of behavior change strategies (Decision 5). Because this project focused on small farmer operations that were exempt from OSHA requirements, CS-CASH relied on providing something of value to the audience and anticipated that the product offered would lead to farmers voluntarily adopting the desired behavior change.

Essential Aspect 3, research in audience analysis and segmentation strategies, was addressed though conducting formative research that focused on understanding the issue from multiple perspectives including barriers and motivators from the audiences' point of view (Decision 2). Behavior change theory also plays a role in understanding the audience.

Essential Aspect 4, use of formative research in product or message design and the pretesting of these materials, was addressed as the planners considered the marketing mix best suited to achieve their objectives (Decision 4). The planners developed two message concepts for promotional materials and then tested those messages with members of the target audience. Products in the form of instructional videos and a brightly colored storage bag were developed to address the barriers to RPD use discovered during research early on in the project. The value of these product offerings is evident in the continued interest in the instructional videos (Table 10.3) and the adaptation of the storage bag to other CS-CASH outreach efforts (Figure 10.2).

Essential Aspect 5, analysis of distribution (or communication) channels was addressed during decisions about behavior change strategies (Decision

5) and implementation (Decision 6). Distributing the instructional videos via a YouTube channel was seen by the expert panel as a convenient way to reach the audiences. The validity of this perspective was established when all of the NIOSH-funded agricultural safety and health centers across the U.S. created a joint YouTube channel to share educational and instructional videos. In addition, promotional messages were distributed via email because previous experience in working with Farm Market ID had shown email to be an effective way of reaching the audience.

Essential Aspect 6, use of the "marketing mix"—that is, using and blending product, price, place, and promotion characteristics in intervention planning and implementation was addressed in decisions about behavior change strategies (Decision 5). Project planners considered all four elements of the marketing mix. Although the final behavior change strategies included in the project do not include a "price" component, planners considered the monetary and nonmonetary costs associated with the use of RPD.

Essential Aspect 7, a process tracking system with both integrative and control functions, was addressed by monitoring open and click-through rates for emails distributed as part of this campaign as well as the number of views of the videos. These metrics were a part of evaluating the project (Decision 6). The control function of process tracking is illustrated by a slight change in wording used on subsequent printing of the orange storage bag where the words "smart farmers" was change to "healthy farmers." Feedback from some members of the audience indicated that "healthy farmers" was more acceptable terminology. The control function is also illustrated by changing branding strategies after the first email "blast" wherein CS-CASH leadership decided that sending the emails under the CS-CASH name and logo would allow greater control of the brand.

Essential Aspect 8, a management process that involves problem analysis, planning, implementation, and feedback functions, was addressed through careful monitoring of the implementation (Decision 5) and evaluation (Decision 6) of the project. Planners and CS-CASH leadership were regularly updated on project metrics and provided input on adjustments made during implementation.

10.9 Conclusion

Formalizing the social marketing planning process resulted in a comprehensive strategy for disseminating key messages and the products associated with this campaign. Using formative research to understand the identified audiences and pretesting to refine messages resulted in messages that contributed to an effective communication strategy. Although the campaign fell short of its objectives, the project demonstrates the efficacy of a planning process that incorporates formative research and clear decision points throughout. This process could be used to plan health behavior change interventions to address other agriculture-related health and safety issues.

Acknowledgment

This project was funded by Central States Center for Agricultural Safety and Health (CS-CASH) NIOSH (U54 OH010162).

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Section III

Respirator Fit

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11

Respirator Fit Testing

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11.1 Overview

Fit testing of respirators is absolutely critical to help minimize the chance of poorly fitting respirators which can lead to reduced respiratory protection and increased exposures to workers. For tight-fitting facepieces, even the smallest pinhole-sized leak at the interface between the facepiece and face can greatly increase exposures. As the human face comes in many shapes and sizes, it is important to find a respirator facepiece that best accommodates the anatomical features of the wearer. Respirator fit testing helps to check whether a good match between a respirator and wearer exists. Fit testing is the only accepted way to determine if a respirator fits properly.

Per Occupational Safety and Health Administration (OSHA) regulation 29 CFR 1910.134(f), before an employee may be required to use any respirator with a negative or positive-pressure tight-fitting facepiece, the employee must be fit tested with the same make, model, style, and size of respirator that will be used in the workplace (OSHA 1998a). Note that the respirator worn for fit testing does not need to be the actual respirator to be worn by the individual in the workplace. Fit testing must be done in accordance with OSHA-accepted fit test protocols listed in 29 CFR 1910.134, Appendix A. Loose-fitting respirators (e.g., hood-style respirators) are exempt from OSHA fit testing requirements. In addition, any tight-fitting positive-pressure respirators must be fit tested in negative pressure mode by temporarily converting them into an air-purifying respirator with appropriate filters (TSI 2015).

Beyond helping ensure that an appropriate make/model/size of respirator is matched to an individual, another important reason for fit testing is to check whether an individual knows how to properly don (i.e., put on) and wear a respirator (TSI 2015). Therefore, the fit test operator should not physically assist the test subject in donning the respirator. Donning a respirator correctly is very important as even an appropriately sized respirator will do little to protect a wearer if worn improperly. In essence, the fit testing event does not replace the need for formal training on respiratory protection; a test subject should arrive at the fit test session with training already completed.

Respirator fit testing is conducted using either a qualitative or quantitative protocol designed to evaluate leakage of a tight-fitting respirator worn by an individual. Qualitative fit testing (QLFT) is somewhat *subjective* in nature as it evaluates an individual's voluntary or involuntary response (i.e., taste, odor, or irritation) to a fit test challenge agent during a series of exercises while wearing a respirator, in order to check whether a respirator seals properly to the face. It is a pass/fail test only. Quantitative fit testing (QNFT) is *objective* and assesses the adequacy of respirator fit by quantifying the amount of leakage into the respirator and does not rely on an individual's voluntary or involuntary response to challenge agents.

Some employers choose to operate their own respirator fit testing program, while other employers, especially smaller ones, will outsource the initial and annual fit testing to various consultants, companies, or clinics. There are several cost considerations associated with operating a fit testing program, including manpower, purchasing QLFT or QNFT equipment/supplies, and purchasing an assortment of dedicated respirators to accommodate workers of various faces shapes and sizes.

A revised 29 CFR 1910.134 Respiratory Protection Standard (OSHA 1998b) was released on January 8, 1998, replacing the original version released in

1971. Many of the changes in the new version pertained to fit testing and superseded all other OSHA fit testing requirements embedded in other OSHA standards, with the exception of tuberculosis (TSI 2012). OSHA had proposed a separate tuberculosis standard which would have provisions for respirator use, but decided that the interim solution for tuberculosis would be continued compliance with the original 1971 version of the Respiratory Protection Standard, recodified as 29 CFR 1910.139 Respiratory Protection for *M. tuberculosis (M. tb).*

A Federal Register Notice published on December 31, 2003 finally withdrew 29 CFR 1910.139, thereafter requiring employers to comply with 29 CFR 1910.134. With the transition to 29 CFR 1910.134, those employees using respirators solely to reduce exposures to *M. tb* now needed to comply with all elements of a respiratory protection program (RPP). This included requirements for medical evaluations, annual fit testing, annual training, and record keeping requirements (3M 2004).

11.2 Frequency of Fit Testing

Per the OSHA respiratory protection standard, fit testing is required before initial use of respirators and at least on an annual basis. This annual fit test requirement came about due to fit test data from four companies during the OSHA rulemaking public comment period. One of these companies reported conducting fit testing every 2 years and found that 7% of employees switched to different respirator sizes or models due to failed fit tests. OSHA considered a 2-year 7% failure rate unacceptable as such employees could be relying on poor-fitting respirators if not fit tested annually (Zhuang et al. 2016).

Beyond the OSHA annual requirement, fit tests should be accomplished whenever a different respirator (i.e., size, style, model, and make) is desired or if changes occur to the employee's physical condition which could affect respirator fit. Such changes include facial scarring, dental issues, cosmetic surgery, or an obvious change in body weight (OSHA 1998a). Zhuang et al. (2016) examined changes in face seal leakage at 6-month intervals; their findings generally supported the OSHA requirements for fit tests on an annual basis and when physical changes to the user have occurred. Although limited to N95 filtering facepiece respirators (FFRs), the study concluded that respirator users who have lost more than 20 pounds should be retested to ensure that the current make/model/size of respirator still fits properly. The greater the weight loss, the more likely that respirator fit will change. Further, as time between fit tests increases, so does the risk of unacceptable fit. For FFRs, if fit testing was conducted annually, 10.4% of users had unacceptable fit. When fit testing was conducted every 2 years, 19.7% had unacceptable fit. Finally, a 3-year interval led to 25.4% with unacceptable fit (Zhuang et al. 2016).

11.3 Fit Testing Qualifications

OSHA requires that employers ensure people administering fit tests be able to perform certain tasks. For QLFT, test administrators must be able to prepare test solutions, calibrate equipment, perform tests properly, recognize invalid tests, and ensure that test equipment is in proper working order. For QNFT, test administrators must be able to calibrate equipment, perform tests properly, recognize invalid tests, calculate fit factors properly, and ensure that test equipment is in proper working order (OSHA 1998b). Similarly, in ANSI/AIHA Z88.10-2010, the standard recommends that personnel be "properly trained" and be able to demonstrate a proficiency in the fit test methods being used (ANSI and AIHA 2010).

In the United Kingdom, concern over the quality of fit testing led to the development of a competency and accreditation scheme called "Fit2Fit." The Fit2Fit RPE (respiratory protection equipment) Fit Test Providers Accreditation Scheme was created by the British Safety Industry Federation (BSIF), along with the Health and Safety Executive (HSE) and other industry stakeholders. This program was formed to confirm the competency of any person performing respirator fit testing (Fit2Fit 2016). It covers four main types of fit testing methods: qualitative (taste test), quantitative using ambient particle count/PortaCount with or without N95 Companion, and quantitative using controlled negative pressure (CNP). Individuals can become accredited in any or all of these types of fit testing by taking an exam and practical assessment. Accredited Fit2Fit testers oversee the practical assessment portion of accreditation. Successfully passing will result in the individual being accredited for the specific type(s) of fit testing for a period of 3 years. A list of accredited individuals is provided at the Fit2Fit website.

11.4 Fit Testing: General Instructions

Before beginning the fit testing, the employer (i.e., fit tester) should show the test subject how to put on a respirator, position it on the face, set strap tension, and determine an acceptable fit. Any special instructions provided by the manufacturer should also be followed. A mirror should be provided to assist the test subject in donning the respirator. Any instruction provided during fit testing should serve as a review only and does not replace the need for training beforehand.

A sufficient number of respirator models and sizes should be made available to accommodate various faces sizes and shapes. These should be NIOSH-certified respirators. A discussion on the NIOSH certification process can be found in Chapter 2. The test subject should be informed that he/she is being asked to select the respirator with the most acceptable fit. To select the most acceptable respirator, the test subject should be instructed to hold each model/size up to the face and eliminate those that obviously do not provide an adequate fit. More acceptable models/sizes should be noted in the event that the preferred respirator does not lead to a passing fit test. In general, if the worker finds the fit of the respirator unacceptable, then another respirator should be chosen.

Once a respirator is chosen, the test subject should don it properly and wear it for at least 5 minutes to assess comfort. If not familiar with using a particular respirator, the test subject should practice adjusting the strap tension several times. A properly fitting respirator should allow positioning on the face and cheeks, placement of the chin, adequate strap tension, good fit across the bridge of the nose, adequate span distance nose-to-chin, and negligible slipping.

11.5 User Seal Check

To ensure an adequate facepiece-to-face seal, a user seal check must be performed whenever a tight-fitting respirator is donned and periodically during use. OSHA requires two different tests to check the seal of the respirator facepiece to the user's face. These are called "user seal checks." One is a negative pressure test and the other is positive pressure. The negative pressure test is performed by first closing off the inlet to the cartridge using the palm of the hand. The user then inhales slightly and holds his/her breath. If there is a good seal, the respirator facepiece should collapse slightly against the face.

For the positive-pressure test, the user closes off the exhalation valve with the palm and then exhales gently. If there is a good seal, a slight positive pressure will build up inside the facepiece. Failure to build up such a pressure indicates a leak, which might also be observable.

Respirator manufacturers may also recommend different methods to check the seal integrity. Employers should refer to manufacturer guidance as well. Regardless of the approach used, any failed user seal checks would warrant that another facepiece be selected and the user seal check re-accomplished. Conducting user seal checks should become a habit for workers and respiratory training should emphasize this practice.

11.6 OSHA Fit Testing Protocols

In 29 CFR 1910.134 Appendix A, Fit Testing Procedures, OSHA describes the requirements for fit testing using QLFT and QNFT. There are several factors to consider before deciding which method to use, including budget, number of workers, and magnitude of potential exposure levels. Generally speaking, QLFT is simpler from a technology standpoint. Buying QLFT equipment and supplies is typically much less expensive than purchasing a QNFT system.

Regardless of which method is chosen, fit tests should not be performed if any facial hair impedes the facepiece-to-face seal (e.g., stubble, beard growth, beard, mustache, or sideburns). Although rates of growth of facial hair arguably vary, "facial hair" is qualified as "more than one day's growth" in the OSHA Inspection Procedures for the Respiratory Protection Standard (OSHA 1998a). Any apparel which interferes with a satisfactory fit should be altered or removed as to avoid any facepiece seal leakage or interference with valve function of tight-fitting respirators. Further, corrective goggles/glasses or other personal protection equipment (e.g., faceshields, protective clothing, and helmets) must not interfere with the seal (OSHA 1998a).

Prior to beginning the fit test, the test exercises should be described to the test subject. Any safety equipment that may be worn during respirator use should be worn during the fit test to check whether it interferes with the fit of the respirator. For tight-fitting atmosphere-supplying and powered air-purifying respirators, negative pressure mode must be used regardless of whether the respirator will be operated in negative or positive-pressure mode (OSHA 1998b).

Table 11.1 lists the exercises required as part of a qualitative or quantitative fit test. The eight exercises are designed to simulate workplace motions and are meant to challenge the fit of the respirator. These exercises have a minimum duration of 1 minute, except "grimace" which is performed for only 15 seconds and only for QNFT, not QLFT. For QNFT, the result from the grimace exercise is excluded from the overall fit factor calculation (TSI 2012). The purpose of "grimacing" is to try and intentionally break the face seal to see if the respirator will reseat to the wearer's face, as validated by measuring the fit factor *after* the grimacing. Grimacing during *qualitative* fit testing is not worthwhile, as it would always result in a failed fit test (TSI 2015).

11.6.1 Qualitative Fit Test Protocols

Qualitative fit tests are relatively inexpensive and simple to conduct, using any of the four OSHA-approved protocols found in 29 CFR 1910.134 Appendix A (OSHA 1998b). These protocols are: isoamyl acetate (IAA), saccharin solution aerosol (mist), Bitrex®, and irritant smoke. See Table 11.2 for a short summary of each protocol. Generally, if the user detects the challenge agent at any time during the fit test, the user then "fails" the test. If no detection occurs, then the fit test is passed and the user is assumed to have a fit factor at least as high as the QLFT was designed to determine, stated as being 100 (TSI 2015).

Although QLFT provides a somewhat inexpensive and a simpler technological solution for fit testing, a drawback is that it is "pass/fail" only and

TABLE 11.1

OSHA Fit Test Exercises

Exercise	Description
1. Normal breathing	In a normal standing position, without talking, the subject shall breathe normally
2. Deep breathing	In a normal standing position, the subject shall breathe slowly and deeply, taking caution as not to hyperventilate
3. Turning head side to side	Standing in place, the subject shall slowly turn his/her head from side to side between the extreme positions on each side. The head shall be held at each extreme momentarily so the subject can inhale at each side
4. Moving head up and down	Standing in place, the subject shall slowly move his/her head up and down. The subject shall be instructed to inhale in the up position (i.e., when looking toward the ceiling)
5. Talking	The subject shall talk out loud slowly and loud enough so as to be heard clearly by the test conductor. The subject can read from a prepared text such as the Rainbow Passage [a], count backward from 100, or recite a memorized poem or song
6. Grimace (QNFT only)	The test subject shall grimace by smiling or frowning
7. Bending over	The test subject shall bend at the waist as if he/she were to touch his/her toes. Jogging in place shall be substituted for this exercise in those test environments such as shroud type QNFT or QLFT units that do not permit bending over at the waist
8. Normal breathing	Same as Exercise 1

Source: Occupational Safety and Health Administration (OSHA). 1998b. Respiratory Protection, 29 CFR 1910.134, Final Rule. *Federal Register Notice*.

[a] Rainbow Passage: "When the sunlight strikes raindrops in the air, they act like a prism and form a rainbow. The rainbow is a division of white light into many beautiful colors. These take the shape of a long round arch, with its path high above, and its two ends apparently beyond the horizon. There is, according to legend, a boiling pot of gold at one end. People look, but no one ever finds it. When a man looks for something beyond reach, his friends say he is looking for the pot of gold at the end of the rainbow."

does not measure leakage. Further, it relies on the user being able to detect the challenge agent being used, which can be problematic as some people lack sensitivity to such agents. If the subject detects (i.e., tastes, smells, or is irritated by) the challenge agent during the fit test, the test is a failure.

Those passing QLFT could claim a *fit factor* of 100, but no more. QLFT is only used for fit testing tight-fitting respirators that are allowed to pass with a minimum fit factor of 100, which are only half-mask respirators. As OSHA requires a fit factor of 500 for full-facepiece respirators, and since there is no approved OSHA QLFT protocol capable of a fit factor greater than 100, QNFT must be used for any tight-fitting full-facepiece respirators (TSI 2015).

TABLE 11.2

Qualitative Fit Tests[a]

Qualitative Fit Test Protocol	Summary of the Protocol	Other Notes
Isoamyl Acetate "Banana Oil"	• Test subject first undergoes an *odor* threshold screening, using two jars—one with water and one with a low concentration of IAA. The jar with IAA must be correctly identified • Upon successfully passing the screening, the test subject will don the respirator with an OV cartridge to then begin the IAA fit test • IAA fit test is conducted inside a soft-sided plastic chamber, with 0.75 mL of IAA on a paper towel or similar material introduced into the chamber • Exercises in Table 11.1 are administered, while using *OV cartridges* on the respirator • Self-reported detection of IAA odor constitutes a "failed" test	• Isoamyl acetate smells like bananas • Some individuals cannot detect odors from IAA, especially at low concentrations • Olfactory fatigue is possible, especially if there is inadvertent excessive/continued exposure • Mixtures used should be prepared in an area separate from fit testing, to help prevent olfactory fatigue
Saccharin Solution Aerosol	• Test subject first undergoes a *taste* threshold screening, by wearing a small test enclosure (hood), with a small hole in front of the nose/mouth. A nebulizer is used to spray the very dilute saccharin threshold check solution into the chamber. The tongue is slightly extended to help detect the sweet taste of the saccharin solution • Upon successfully passing the screening, a second nebulizer is used to spray the stronger fit test solution into the enclosure for the saccharin solution fit test • Exercises in Table 11.1 are administered, while using *particulate filters* on the respirator • Self-reported taste of saccharin constitutes a "failed" test	• Saccharin is sweet-tasting • aka sodium saccharin • Some individuals cannot taste the sweetness of saccharin, especially at low concentrations • No eating, drinking (except plain water), smoking, or chewing gum for 15 minutes before the test • Saccharin aerosol needs to be replenished every 30 seconds • Nebulizer bulb needs to be repeatedly squeezed per test • Nebulizers can clog and must be checked periodically

(Continued)

TABLE 11.2 (*Continued*)

Qualitative Fit Tests[a]

Qualitative Fit Test Protocol	Summary of the Protocol	Other Notes
Bitrex®	• Follows the protocol for saccharin solution, except for the challenge agent used	• Bitrex is bitter-tasting; commonly used as a "taste aversion agent" (deterrent) • aka "denatonium benzoate" • Some individuals cannot taste the bitterness of Bitrex, especially at low concentrations • No eating, drinking (except plain water), smoking, or chewing gum for 15 minutes before the test • Nebulizer bulb needs to be repeatedly squeezed per test
Irritant Smoke	• Test subject first undergoes an *irritant smoke* threshold screening, by breaking both ends of the ventilation smoke tube and connecting to a low flow pump or aspirator squeeze bulb. A small puff should be directed toward the test subject to allow them to become familiar with its irritant properties • Upon successful passing the screening, the test subject will don the respirator and perform a user seal check. Eyes will be kept closed. Smoke will be directed toward the face seal area to ensure a good seal prior to beginning the exercises • Exercises in Table 11.1 are administered, while using *high-efficiency particulate air (HEPA) or P100 series filters* on the respirator. Continually challenge the test subject with irritant smoke, directed around the perimeter of the respirator at a distance of six inches • Detection of irritant smoke (self-reported or involuntary response) constitutes a "failed" test • Those who pass will be administered a second sensitivity check. Failure to evoke a response will void the fit test	• Irritant smoke is stannic chloride, $SnCl_4$ • Use only stannic chloride-based ventilation smoke tubes • Smoke can be irritating to the eyes, lungs, and nasal passages. Exposures should be minimized • No test enclosure or hood is used

---

[a] See 29 CFR 1910.134 Appendix A (OSHA 1998b) for specifics on QLFT.

11.6.1.1 Isoamyl Acetate Qualitative Fit Testing Protocol

Probably the most commonly used qualitative test method is IAA vapor, which is fondly nicknamed "banana oil" for its distinct banana-like odor. The test protocol involves two steps, the first being the odor threshold screening to detect sensitivity to IAA (or lack thereof) and the second step being the actual fit test.

For the odor threshold screening, the test subject is asked to sniff two separate 1-liter jars—one containing a small amount of IAA in odor-free water ("odor test" jar) and the other containing only odor-free water ("test blank" jar). The jar containing IAA is prepared in a separate room, away from the fit test area, in order to avoid olfactory fatigue of the test subject. Labeled "1" and "2," or similar, the test subject must correctly identify which jar contains IAA. Correctly doing so indicates that the test subject can detect low levels of IAA and is thereby able to continue with the IAA fit test.

The IAA fit test must be conducted in a fit test chamber, constructed using a 55-gallon drum liner or similar plastic sheeting, suspended and inverted over a 2-foot diameter frame so that the top of the chamber is approximately 6 inches above the test subject's head. The test subject will wear a respirator with organic vapor (OV) cartridges, even if particulate matter is the basis for requiring the respirator to be worn. This allows the OV cartridge to remove IAA from inhaled air, resulting in any detected IAA to be caused only by leakage into the respirator.

A paper towel or similar absorbent material will be wet with 0.75 mL of pure IAA and then is hung on a hook at the top of the chamber. The test concentration is allowed to stabilize for 2 minutes. The fit test exercises (Table 11.1) are administered, facilitated by taping a copy of the exercises inside the test chamber. If the user detects the odor of IAA, the test is considered a "fail" and the user exits the test area, repeats the odor detection test, then selects a new respirator to reattempt the fit test. If the odor detection test is failed, then the subject shall wait at least 5 minutes to allow odor sensitivity to return.

11.6.1.2 Saccharin Solution Aerosol Qualitative Fit Testing Protocol

A second type of QLFT is the saccharin solution aerosol fit testing protocol. Here, sodium saccharin is the test agent. The test subject first undergoes a *taste* threshold screening by wearing a small test enclosure (hood) with a small hole in front of the nose/mouth. A DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent is used to spray the very dilute saccharin threshold check solution into the chamber (i.e., 0.83 grams of sodium saccharin diluted into 100 mm of warm water) (Figure 11.1). The test administrator manually squeezes the nebulizer bulb to loft a suitable amount of saccharin aerosol in the test enclosure. The test subject is instructed to breathe through his/her mouth with the tongue slightly extended to help detect the sweet taste of the

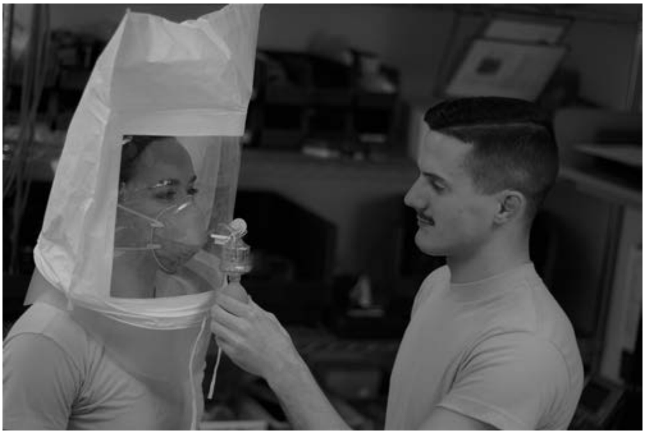

FIGURE 11.1
Example of a qualitative fit test using a nebulizer and following the saccharin or Bitrex solution protocols. (Courtesy of Alex W. Egan.)

saccharin solution. If the test subject can adequately detect saccharin using the sense of taste, then the fit test protocol can begin.

For the actual fit test using saccharin, a second nebulizer with a stronger solution is used. The test subject may not eat, drink (except plain water), smoke, or chew gum for 15 minutes prior to the test. The test subject will don the test enclosure used for the taste threshold screening while wearing the respirator equipped with a particulate filter. A second nebulizer, filled with a stronger test solution of saccharin (i.e., 83 grams of sodium saccharin diluted into 100 milliliters of warm water), is used to spray test solution into the enclosure for the fit test. Once again, the test subject will breathe through a slightly open mouth with the tongue extended, in order to verify that saccharin can be tasted. The test administrator uses the same number of squeezes necessary for detection during the threshold screening prior to starting the fit test exercises. The aerosol concentration of saccharin should be replenished every 30 seconds using half the number of squeezes of the nebulizer bulb. Self-reported detection (taste) of the saccharin solution constitutes a failed fit test. A different respirator should be chosen and the taste threshold screening and fit testing must be repeated.

Previously, NIOSH had recommended against using the saccharin fit test because of saccharin being classified as a potential carcinogen (Bollinger 2004). NIOSH later re-examined the potential risk to fit test subjects (Bollinger 2004, NIOSH 1999), concluding that the risk to subjects was extremely low and is again supportive of saccharin as a challenge agent.

11.6.1.3 Bitrex® Solution Aerosol Qualitative Fit Testing Protocol

The third type of QLFT relies on Bitrex (denatonium benzoate) solution as the challenge agent. Bitrex is an FDA-approved flavoring, most commonly used as an aversion agent for various toxic household chemicals to deter young children from ingesting. This protocol follows the procedures for the saccharin protocol except for reliance on detection of the bitter taste of Bitrex.

11.6.1.4 Irritant Smoke (Stannic Chloride) Qualitative Fit Testing Protocol

The irritant smoke test relies on stannic chloride ventilation "smoke tubes," which were originally designed to study the behavior of building ventilation systems, to challenge the seal between the respirator facepiece and the wearer's face. Stannic chloride in smoke tubes reacts with ambient moisture to form white hydrogen chloride "smoke." The resulting smoke stream is directed toward the respirator and an inadequate seal is usually indicated by an involuntary response (e.g., coughing, gagging, and watery eyes) by the wearer (NIOSH 2004). These responses are the same adverse health effects against which the hydrogen chloride exposure limits are intended to protect, thereby prompting NIOSH to recommend against the use of irritant smoke (stannic chloride) for QLFT. Although OSHA still allows use of the irritant smoke protocol, it prohibited use of a chamber or hood during the fit test and required that eyes be kept closed during the protocol (TSI 2015).

11.6.2 Quantitative Fit Test Protocols

Quantitative fit testing (QNFT) provides a more automated means of fit testing and directly measures a test substance both inside and outside the respirator to estimate the facepiece seal performance via the "fit factor" or it directly measures leakage into the respirator (Colton 2011, TSI 2015). It differs from qualitative fit testing as it does not depend on the wearer's voluntary or involuntary response to a challenge agent, essentially taking the wearer's sensitivity and subjectivity out of the process. Any respirator requiring a fit factor (not "assigned protection factor") above 100 must be fit tested using QNFT (TSI 2015).

Currently, there are three OSHA-approved methods for quantitative fit testing of respirators per 29 CFR 1910.134 Appendix A: (1) generated aerosol (oil mist/chamber), (2) ambient aerosol, using condensation nuclei counter (CNC) technology (e.g., TSI PortaCount®), and (3) controlled negative pressure (CNP) technology (e.g., Occupational Health Dynamics [OHD] Quantifit®). A summary of the three QNFT protocols is shown in Table 11.3.

11.6.2.1 Generated Aerosol Quantitative Fit Testing Protocol

The generated aerosol fit testing protocol is the oldest of three QNFT protocols recognized by OSHA. For this protocol, the respirator wearer stands in the chamber, and an aerosol generator is used to produce a high concentration

TABLE 11.3

Quantitative Fit Tests[a]

Type of Quantitative Fit Test	Summary of the Protocol	Other Notes
Generated Aerosol (Oil/Mist Chamber)	• Generates a test substance (aerosol) inside a small chamber where the respirator wearer stands • A photometer measures the aerosol concentration both outside and inside the respirator	• Uses oil mist (e.g., corn oil, salt mist, etc.) as the test substance
Ambient Aerosol (Condensation nuclei counter)	• Fit test instrument uses isopropyl alcohol vapor to condense on ambient particles and "grow" them to sizes suitable for counting • Particles are counted both outside and inside the respirator • Fit factor = concentration outside the respirator/concentration inside the respirator	• Uses ambient particles as the test substance • Candles, particle generators, etc., may be necessary to increase ambient particle levels • Available commercially as: TSI PortaCount® series
Controlled Negative Pressure	• Respirator inlets are capped off using special adapters to create an air-tight seal • Fit test instrument generates a slight negative pressure inside the facepiece to simulate inhalation • Any volume of air removed by the instrument during this short period of negative pressure represents air leakage into the respirator (a poor fit)	• Does not rely on ambient particles • Uses a five-exercise CNP REDON protocol (Table 11.4) • Available commercially as: OHD Quantifit (formerly Dynatech FitTester 3000®)

[a] See 29 CFR 1910.134 Appendix A (OSHA 1998b) for more specifics on QNFT and these protocols.

of usually corn oil or sodium chloride (NaCl) mist inside the small chamber. The respirator wearer then performs the series of exercises described in Table 11.1. Use of a high concentration of challenge agent had been necessary as older photometer-based aerosol detection equipment could not measure very low concentrations of aerosol that could exist inside the respirator facepiece if leakage occurred. A "fit factor" is the ratio of the average count of ambient particles outside the mask over the average count of particles inside the mask (Equation 11.1).

$$\text{Fit factor} = \frac{\text{Concentration outside the mask}}{\text{Concentration inside the mask}} \tag{11.1}$$

11.6.2.2 Ambient Aerosol Condensation Nuclei Counter Quantitative Fit Testing Protocol

Perhaps the most commonly used quantitative fit test equipment using ambient aerosol CNC technology is the TSI PortaCount® family of respirator fit testing instruments. Designed to overcome the subjective results provided by qualitative fit testing, the PortaCount calculates an overall fit factor which is a weighted average of the individual fit factors for each of the eight exercises described earlier in Table 11.1 (Equation 11.2). A high fit factor is desirable, and the PortaCount is typically capable of measuring fit factors of 10,000 and higher (TSI 2015). Use of the PortaCount provides relatively fast fit testing with real-time feedback to the respirator wearer which can enhance respirator training (Figure 11.2). Passing a QNFT demonstrates that the respirator facepiece is properly sized for the wearer and is donned correctly.

$$\text{Overall fit factor} = \frac{N}{1/\text{ff}_1 + 1/\text{ff}_2 + \cdots + 1/\text{ff}_N} \tag{11.2}$$

where

N = the number of exercises

ff_1 = fit factor for the first exercise

ff_2 = fit factor for the second exercise

ff_N = fit factor for the nth exercise.

The PortaCount relies on an isopropyl alcohol-soaked wick placed in the instrument to generate vapors which condense on small particles. This "growing" of particles allows them to be detected by a light-beam counting

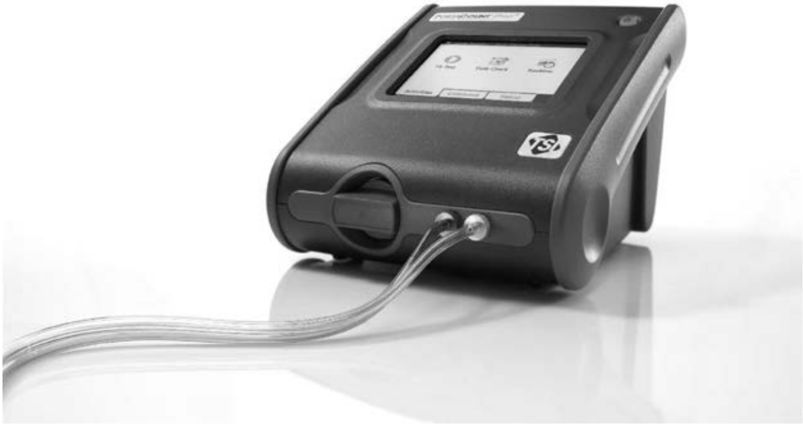

FIGURE 11.2
TSI PortaCount Pro+® CNC quantitative fit test instrument. (Courtesy of TSI Inc.)

device which enables quantification of fit to be calculated via the fit factor. As the CNC technology is dependent on particle counting, an adequate number of particles must be present in ambient air. If not, then burning a candle or use of a particle generator, etc., will be necessary to increase the ambient particle count.

For fit testing, the employer must provide "probed" versions of each respirator type to allow the PortaCount to count the particles inside the facepiece. Examples of probed respirators are shown alongside a PortaCount in Figure 11.3. Previously, elastomeric respirators (half- and full-facepiece) could be purchased with metal probes already installed by the respirator manufacturer for workers to wear during QNFT. For FFRs, metal fittings were provided with the PortaCount to easily install the probes.

In recent years, manufacturers began selling "fit test adapters kits" which provide an adapter incorporated into a high-efficiency filter specific to the manufacturer/make/model of respirator. A benefit of this approach is that workers can wear their own respirator for the fit test which can give them and the employer confidence that the actual respirator worn performs as well as employer-provided probed respirators described earlier.

For fit testing using the PortaCount, workers must use particulate filters even though they may be required to use chemical cartridges in the workplace. Chemical cartridges do not effectively stop ambient particles from entering the respirator, and use of high-efficiency filters helps ensure that any particles counted inside the mask are attributable to seal leaks only (TSI 2015). Further, some chemical cartridges can release small amounts of particles from the sorbent material inside a chemical cartridge, thus potentially biasing results.

The probed respirator is connected to the PortaCount using the "blue and clear twin tubing" (Figures 11.2 and 11.4) which allows particles to be counted both inside and outside the respirator during a fit test. The clear tubing connects to the respirator, while the blue tubing opens to the ambient atmosphere. Before beginning the QNFT, the respirator should be worn for at least 5 minutes to assess comfort and allow ambient air particles trapped in the mask during donning to be purged. Due to the inherently larger volume of air trapped inside the facepiece, a full-face respirator will take longer to fully purge.

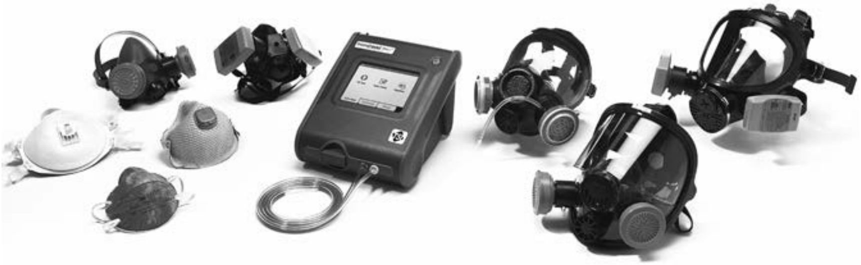

FIGURE 11.3
Examples of "probed" respirators, ready to be used for QNFT. (Courtesy of TSI Inc.)

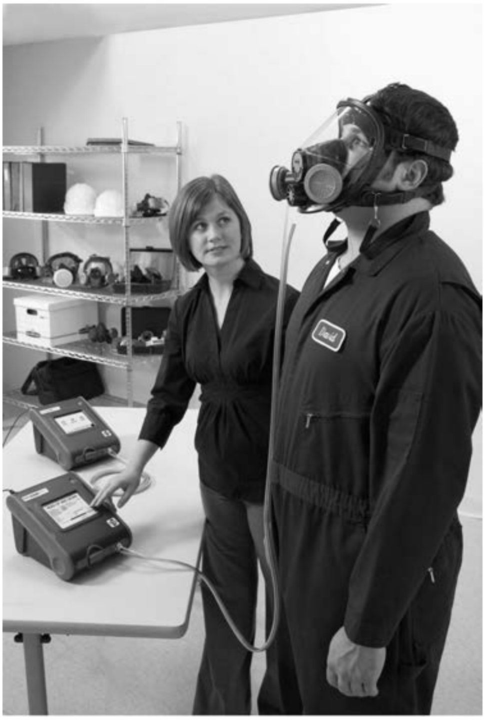

FIGURE 11.4
A worker undergoing quantitative fit testing using a TSI PortaCount fit tester and the CNC protocol. (Courtesy of TSI Inc.)

NIOSH-approved N95 FFRs are commonly used in industrial workplaces, hospitals, and other healthcare settings. As they are "tight-fitting," respirator fit testing is necessary. A challenge with N95 FFRs is that, by design, they are allowed up to 5% penetration under worst-case conditions. This otherwise acceptable filter penetration by ambient aerosols may lead to erroneously low QNFT fit factors (Janssen et al. 2003). The legacy TSI PortaCount Pro devices were designed to quantitatively fit test tight-fitting half-mask and full-facepiece respirators which are >99% efficient. To accommodate N95 FFRs (i.e., 95% efficiency), TSI developed the N95 Companion™ and later produced an upgraded PortaCount model, the PortaCount Pro+ Respirator Fit Tester, with built-in N95 Companion technology. This technology basically limits the detection of particles to a small size range (40–60 nm) associated with the most penetrating particle size (MPPS) for NIOSH-approved FFRs containing electrostatic filter media. Over this size range, filter penetration by particles is very minimal, thus ensuring that particles counted inside the respirator are likely attributable to facepiece-to-face leakage and not direct penetration through the filter (Rengasamy 2012).

11.6.2.3 Controlled Negative Pressure Quantitative Fit Testing Protocol

CNP is a fit testing technology that has been around since the early 1990s and was accepted by OSHA in 1998. Unlike other methods for fit testing, CNP is able to directly measure respirator leakage. The OHD Quantifit® is perhaps the most common CNP-based fit testing instrument currently on the market. The associated CNP REDON respirator fit test protocol is approved by OSHA and appears in 29 CFR 1910.134 Appendix A. The Quantifit replaced the former Dynatech FitTester 3000® instrument (Figure 11.5).

When using the CNP REDON protocol, the respirator inlets must first be capped off with leak-tight test adapters to seal the normal air pathways into the respirator. With the respirator is donned and the worker holding his or her breath, a slight vacuum (simulating inhalation) is applied by the Quantifit instrument to detect any respirator leakage. Any volume of air removed by the Quantifit during this short-time interval represents the leak rate into the respirator, expressed in cubic centimeters per minute (cc/min) (OHD 2016). Unlike CNC technology (e.g., TSI PortaCount), the Quantifit CNP instrument does not rely on counting particles to determine fit integrity and thus avoids issues with low ambient particle counts, workers having smoked within a few minutes of the fit test, etc.

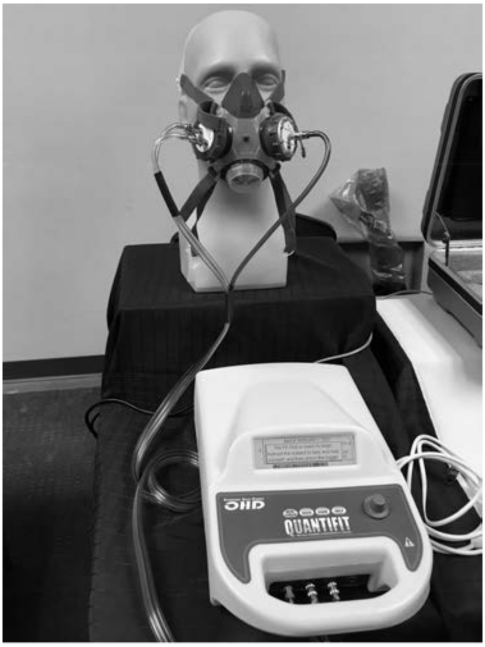

FIGURE 11.5
The Occupational Health Dynamics Quantifit, a CNP quantitative fit testing instrument. (Courtesy of Dirk Yamamoto.)

TABLE 11.4

CNP REDON Quantitative Fit Testing Protocol[a]

Exercises	Exercise Procedure	Measurement Procedure
1. Facing forward	Stand and breathe normally, without talking, for 30 seconds	Face forward, while holding breath for 10 seconds
2. Bending over	Bend at the waist, as if going to touch his or her toes, for 30 seconds	Face parallel to the floor, while holding breath for 10 seconds
3. Head shaking	For about three seconds, shake head back and forth vigorously several times while shouting	Face forward, while holding breath for 10 seconds
4. REDON 1	Remove the respirator mask, loosen all facepiece straps, and then redon the respirator mask	Face forward, while holding breath for 10 seconds
5. REDON2	Remove the respirator mask, loosen all facepiece straps, and then redon the respirator mask	Face forward, while holding breath for 10 seconds

[a] See 29 CFR 1910.134 Appendix A (OSHA 1998b) for specifics on Quantifit CNP REDON fit testing protocol.

Fit testing using the Quantifit requires following the five-exercise CNP REDON fit testing protocol in Table 11.4, which is different from the eight-exercise protocol shown previously in Table 11.1. Exercises include facing forward while breathing normally, bending at the waist, shaking the head vigorously, and redonning the respirator twice. Each exercise includes holding the breath for 10 seconds to allow the Quantifit to create the slight vacuum. Following successful completion of the exercises, the test administrator must ask each test subject about the comfort of the respirator. If declared unacceptable by the test subject, another respirator model should be chosen and the protocol is repeated. With a shorter protocol, the Quantifit can lead to faster fit tests than the PortaCount.

Note that CNP technology cannot be used to fit N95 FFRs since there is no practical way to build up the slight vacuum (i.e., stop outside air from entering the respirator), as the mask and filter are one and the same and readily allow airflow into the facepiece.

11.7 New Fit Test Protocols

Per 29 CFR 1910.134 Appendix A (OSHA 1998b), additional fit test protocols (beyond QLFT, QNFT CNC, and CNP, etc.) can be submitted to OSHA for approval. Any submissions must include a test report prepared by an independent government research laboratory (e.g., Lawrence Livermore National Laboratory or the National Institute for Standards and Technology) to validate the candidate protocol being accurate and reliable. As an alternative, an article from a "peer-reviewed industrial hygiene journal" describing the protocol and explaining how test data support the accuracy and reliability of the protocol can be submitted. If adequate documentation is provided, OSHA will initiate rulemaking under section 6(b)(7) of the OSH Act to determine whether the protocol will appear as a new approved protocol in Appendix A.

11.8 Fit Testing Personnel: AIHA® Body of Knowledge

Founded in 1939, the American Industrial Hygiene Association (AIHA®) is one of the largest international associations dedicated to serving the needs of industrial/occupational hygiene professionals worldwide. In 2014–2015, AIHA and its appointed members and volunteers worked to develop a technical framework which outlines the knowledge and skills representing competency with respect to RPP administration and fit testing (AIHA 2015). Using a panel of subject matter experts, a Body of Knowledge (BoK) document was developed to represent the critical knowledge and skills required for employees/users, supervisors, RPP administrators, and fit testers. The BoK focused on the key areas of RPP requirements, medical evaluations, training, and respirator fit testing.

The BoK summarizes fit testing knowledge and skills as follows (adapted from AIHA 2015):

Employee/User Level:

- Understands the need to be medically evaluated and trained in specific respirator use before a fit test
- Demonstrates an understanding of requirements for completing an initial fit test and retest at the frequency required by the RPP
- Identifies respirator brand, model, material type, and size with which the employee has previously passed a fit test
- Knows what personal protective equipment (PPE) will affect respirator fit

Supervisor Level (in addition to Employee/User Level knowledge):

- Identifies required training and fit testing for the type of device the employee wears
- Understands requirements for fit test status to be current
- Understands the physical requirements for employees being fitted with a respirator or tested with a respiratory protection device, as applicable

- Recognizes physical changes that would require an employee to be retested (e.g., weight loss/gain, dentures)
- Ensures the employee takes his or her PPE along for fit test

RPP Administrator (in addition to Supervisor Level knowledge):

- Identifies technical specifications of the fit testing equipment
- Recognizes respirator-specific testing protocols to be followed during fit tests
- Identifies technical requirements to conduct and document fit using qualitative and quantitative methods, each as applicable
- Establishes the fit tester qualification to be capable of operating fit test equipment, interpreting fit test results, and diagnosing/troubleshooting equipment faults
- Evaluates fit tester competence
- Considers the results of a fit test in selecting the appropriate respirator

Fit Tester Level:

- Follows quantitative (QNFT) and/or qualitative (QLFT) fit test protocols and knows when each is applicable
- Follows proper protocols when fit testing an employee who wears contact lenses
- Follows proper protocols when fit testing an employee who wears glasses
- Conducts troubleshooting for fit test equipment
- Identifies respirator brand, model, material type, size, and typical fitting characteristic
- Identifies risks posed to employees by irritants used in QLFT, if applicable
- Identifies technical specifications of the fit testing equipment
- Integrates hoods and other PPE to determine whether other PPE affects respirator fit
- Interprets failed fit tests, low overall fit factors, and suspicious high overall fit factors
- Recognize physical changes that would require an employee to be retested (e.g., weight loss/gain, dentures)
- Select or create an appropriate environment for the fit test
- Demonstrates an understanding of proper operation of the fit testing equipment and interpretation of fit test results

- Understands the importance of respirator comfort to ensure effectiveness of the fit test
- Understands the physical requirements of the work assignment for employees being fitted with a respirator or tested with a respirator, as applicable

11.9 Key Terms (OSHA 2009)

Assigned protection factor (APF): The workplace level of respiratory protection that a respirator or class of respirators is expected to provide to employees when the employer implements a continuing, effective RPP.

Fit factor: A quantitative estimate of the fit of a particular respirator to a specific individual; typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

Maximum use concentration (MUC): Maximum atmospheric concentration of a hazardous substance from which an employee can be expected to be protected when wearing a respirator; determined mathematically by multiplying the APF by the permissible exposure limit, short-term exposure limit, or ceiling limit.

Qualitative fit test (QLFT): A pass/fail test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.

Quantitative fit test (QNFT): An assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

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12

Performance of Elastomeric Respirators against Ultrafine Combustion Particles

Xinjian "Kevin" He and Sergey A. Grinshpun

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12.1 Introduction

Smoke generated from a fire consists primarily of fine ($\leq$1 μm) and ultrafine ($\leq$0.1 μm) particles. These smoke particles contain a variety of reactive free radicals and other chemical compounds, which pose a potential health risk (Leonard et al., 2007). Baxter et al. (2010) reported that more than 70% (by number) of smoke particles present during fire knockdown and overhaul are ultrafine. Given the overall particle surface area, ultrafine particles can be toxicologically more reactive than those of larger sizes (Lam et al., 2004; Shvedova et al., 2005). Exposure to fine particles at various workplace environments has been associated with impairment of cardiovascular function and other adverse health outcomes. One way to reduce the inhalation aerosol exposure is to wear respiratory protective devices. The performance of respirators has been evaluated in multiple studies using different challenge aerosols (Bałazy et al., 2006a; Huang et al., 2007; Eninger et al., 2008; Shaffer and Rengasamy, 2009; Cho et al., 2010a; Rengasamy and Eimer, 2011). In most respirator evaluation studies, the challenge aerosol was charge-neutralized/equilibrated. Limited peer-reviewed publications addressed the performance of respirators against combustion aerosols, which feature different particle shape, density, electric charge, and other characteristics.

Among various occupations, which are associated with the workers' exposure to combustion aerosols, firefighters are likely to face the highest exposure level and inhalation dose. Respirators used for structural firefighting should meet the certification requirements of the National Institute for Occupational Safety and Health (NIOSH) and the National Fire Protection Association (NFPA) (NFPA, 1981; NIOSH, 1995). Remarkably, there is very limited information on the efficiency of full facepieces widely used by firefighters involved in active fire extinguishing operations. During fire overhaul (after the fire has been extinguished), firefighters enter the structure to examine areas for possible reignition. At that stage, firefighters may use elastomeric half-mask respirators equipped with highly efficient P100 filters (Bolstad-Johnson et al., 2000; Burgess et al., 2001). When subjected to the NIOSH respirator certification test, a P100 filter must provide at least a 99.97% efficiency when challenged to polydisperse dioctyl phthalate (DOP) particles having a count median diameter (CMD) of 185 ± 20 nm and a geometric standard deviation (GSD) of <1.60 (Shaffer and Rengasamy, 2009).

While numerous studies have been conducted to determine the filter efficiency of commercially available respirators, the respirator performance is affected not only by filter efficiency but also by face seal leakage. Furthermore, several studies have shown that particle penetration through face seal leakage may be much higher than through the filter medium (Coffey et al., 1998; Zhuang et al., 1998; Grinshpun et al., 2009; Cho et al., 2010b). To account for these two penetration pathways, NIOSH has proposed the total inward leakage (TIL) concept for testing respirators. However, the current NIOSH TIL test does not consider particle size, as it is based on non-size-selective measurement. TIL was investigated as a function of particle size for aerodynamic diameters ranging from 0.04 to 1.3 μm in a study performed with N95 respirators and surgical masks (Lee et al., 2008). The lowest protection factors (PFs) were observed in the size range of 0.04–0.2 μm, which includes the ultrafine fraction. As to the face seal leaks, Oestenstad and Perkins (1992) who studied a half-mask respirator on 73 subjects found the respirator performance to be strongly affected by leaks at the nose and chin areas.

Limited data are available about the ultrafine particle penetration through face seal leaks of elastomeric respirators even for a relatively simple case when the breathing flow rate is assumed to be constant. It is much more complex to quantify the particle penetration under actual breathing conditions (when the air flow through a respirator is not constant but has a cyclic nature). Early researchers addressed the effects of face seal leakage on particle penetration (Hinds and Kraske, 1987; Chen et al., 1990; Chen and Willeke, 1992). A recent study conducted by Rengasamy and Eimer (2011) investigated the TIL for filtering facepiece respirators (FFRs), and reported that penetration increased with increasing leak size. With smaller size leaks (<1.65 mm), the penetration values measured for 50 nm size particles were approximately 2-fold higher than the values determined for 8 and 400 nm size particles. However, the quoted studies were conducted using constant flow with artificially induced leaks. Cho et al. (2010b) investigated a more realistic face seal leakage by partially sealing a N95 respirator on a manikin face with a sinusoidal breathing pattern established by a breathing simulator. They showed that most of particles penetrated into the respirator through the face seal leakage, rather than through the filter. A similar conclusion was drawn by Grinshpun et al. (2009) for a N95 FFR and a surgical mask.

To investigate the performance of elastomeric respirators against ultrafine combustion particles originating from the combustion of wood, paper, and plastic, a series of experiments were conducted by He et al. (2013a,b) to examine the effects of inhalation flow, combustion material, and face seal leakage on overall (non-size-selective) and size-selective aerosol particle penetration through elastomeric half and full facepiece respirators equipped with P100 filters. In this chapter, the experimental design, results, and conclusions of the above-quoted studies are presented.

12.2 Materials and Methods

12.2.1 Experimental Design

The experimental setup for investigating particle penetration through the respirator is schematically shown in Figure 12.1. Inside the exposure chamber

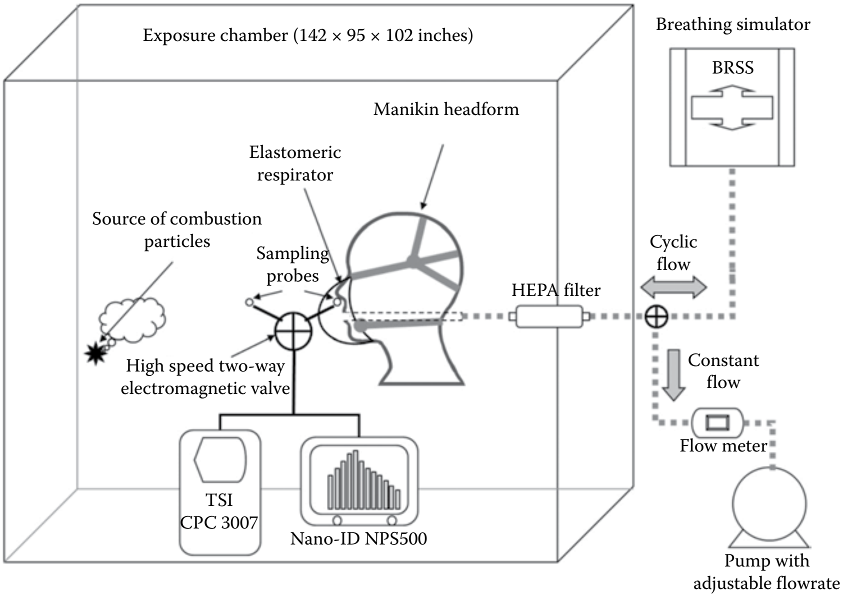
Exposure chamber (142 × 95 × 102 inches)
Breathing simulator
BRSS
Manikin headform
Elastomeric respirator
Source of combustion particles
Sampling probes
Cyclic flow
HEPA filter
High speed two-way electromagnetic valve
Constant flow
Flow meter
TSI CPC 3007
Nano-ID NPS500
Pump with adjustable flowrate

FIGURE 12.1
Experimental setup.

(142 × 95 × 102 inches, L × W × H), the tested respirator was donned on a manikin headform made of hard plastic (Allen Display^{SM} Model: Full round molded male manikin display head). A copper pipe (1 inch diameter) was installed into the headform to simulate airflow through the upper respiratory tract. One end of the pipe was sealed between the upper and lower lips of the manikin. Tests were conducted at three cyclic flows, with mean inspiratory flows (MIFs) of 30, 85, and 135 L/min. These flows represent breathing at medium, high, and strenuous workloads (Lafortuna et al., 1984; Anderson et al., 2006). The cyclic breathing was simulated by an electromechanical Breathing Recording and Simulation System (BRSS) (Koken Ltd., Tokyo, Japan) with a high efficiency particulate air (HEPA) filter placed in between to keep particles from reentering into the respirator cavity with the exhalation air flow. The BRSS consists of an electromechanical drive-cylinder and two air cylinders connected to each other. A sinusoidal air flow is generated as the electromechanical cylinder moves back (inspiratory duration, half a period) and forth (expiratory duration, half a period) (Haruta et al., 2008). One constant flow (30 L/min) was created by a vacuum pump (Model: G272X, Doerr Electric Corp., Cedarburg, WI) to investigate the effects of the flow type (constant vs. cyclic). The aerosol concentrations inside and outside of the respirator were measured with a condensation particle counter (TSI CPC, Model: 3007, TSI Inc., Minneapolis, MN) which detects particles in a size range from 0.01 to >1.0 μm (non-size-selective), and a nanoparticle spectrometer (Model: Nano-ID NPS500, Naneum Ltd., Kent, UK) for the size-selective

measurements. Particle concentration was measured inside (C_{in}) and outside (C_{out}) of the respirator. Particle penetration (P) through the respirator was determined as C_{in}/C_{out}.

12.2.2 Respirators and Test Conditions

Two types of respirators were tested: (1) half-mask elastomeric respirator (size: medium) equipped with two P100 filters and (2) full facepiece elastomeric respirator (size: medium) equipped with the same type of P100 filters.

Nose, chin, and cheek have been identified as common facepiece leak locations (Oestenstad and Perkins, 1992; Oestenstad and Bartolucci, 2010; Crutchfield and Park, 1997). To examine the effect of face seal leakage on the performance of the respirator, four sealing conditions ("unsealed", "nose-only sealed", "nose and chin sealed", and "fully sealed") were established when testing the half-mask respirator. For the full facepiece respirator, only two sealing conditions ("unsealed" and "fully sealed") were used because our pilot study revealed that these two conditions produced similar penetration levels, which made it unnecessary to evaluate partially sealed conditions. A silicone sealant was applied to the respirator when it was necessary to seal the facepiece to the manikin. The fully sealed condition essentially targeted the efficiency of the P100 filters installed on the half-mask respirator assuming no penetration through the exhalation valve. The unsealed and partially sealed conditions permitted evaluation for both penetration pathways: filter penetration and face seal leakage. Sealing configurations for the half-mask with "nose-only" and "nose and chin" sealing conditions are shown in Figure 12.2. Respirator straps were tightened and placed around the manikin's head and neck as conventionally used. For each sealing condition, once the respirator was positioned, it was not removed until another sealing condition was evaluated.

Three combustion aerosols were generated by burning the following materials inside the test chamber: wood (Barbecue (BBQ) long match, 0.23 ± 0.03 g), paper (multifold brown paper towel, 0.25 ± 0.04 g), and plastic (Ziploc™ plastic sandwich bags, single layer, 0.24 ± 0.04 g). Wood, paper, and

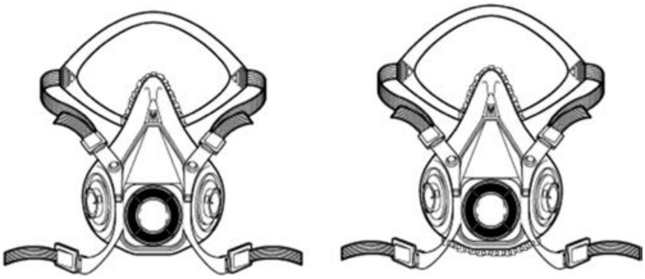

FIGURE 12.2
"Nose-only" and "nose and chin" sealed half-mask respirators. Respirator total length: 16 inches. Nose-only sealed length: 5 inches. Nose and chin sealed length: 4 inches.

TABLE 12.1

Summary of Experimental Conditions

Variables	Levels	
Respirator type	Half-mask	Full mask
Sealing condition	4 (unsealed, nose-only sealed, nose and chin sealed, fully sealed)	2 (unsealed, fully sealed)
Burning material	3 (paper, wood, plastic)	3 (paper, wood, plastic)
Manikin breathing rate	1 constant (30 L/min) 3 cyclic (30, 85, 135 L/min)	1 constant (30 L/min) 3 cyclic (30, 85, 135 L/min)

plastic are the most common materials encountered by firefighters during fire activities. All three materials were ignited by a long reach lighter and burnt separately inside the testing chamber. The aerosol measurements were initiated 15 min after burning to allow the combustion aerosol to reach a homogenous concentration. It is noted that aerosol particles originated by combustion are usually highly charged; unlike many earlier investigations, no charge neutralization or equilibration was conducted in this study to preserve the original properties of combustion particles.

For each combination of the test conditions, the experiment was repeated four times. The manikin breathing flow with three replicates was completely randomized throughout the entire study. A summary of experimental conditions is listed in Table 12.1.

12.2.3 Data Analysis

Descriptive and inferential statistical analyses were performed using SAS version 9.2 (SAS Institute Inc., Cary, NC). For each combination of experimental conditions, the mean value of the total penetration and standard deviation were calculated from the three replicates. Analysis of variance (ANOVA) with Tukey's range test and paired *t*-test were performed to study effects of sealing condition, burning material, manikin breathing rate, and particle size on aerosol penetration value. *P*-values of <0.05 were considered to represent significant differences in the outcomes.

12.3 Results and Discussion

12.3.1 Particle Size Distribution of Combustion Aerosols

Prior to the experiments involving respirators, challenge aerosols—produced by combustion of wood, paper, and plastic, respectively—were characterized with respect to their particle size distributions determined with a nanoparticle spectrometer (Model: Nano-ID NPS500, Particle Measuring System, Inc., Boulder, CO). This instrument is capable of measuring particle diameter in a range of approximately 5–500 nm. Particle size distributions of the three combustion aerosols measured at 10, 30, 50, 70, and 90 min after the burning stopped are shown in Figure 12.3. The peak particle size for wood combustion aerosol was around 45 nm, and 95% of the particles fell within the size range of 20–200 nm. The peak size for paper and plastic combustion aerosols were 56 and 89 nm, respectively, with 95% of the particles falling in size ranges of 20–200 and 20–300 nm, respectively. In general, wood combustion produced smaller particles; all three peak concentrations were observed at particle sizes below 100 nm. More than 70% of particles generated by combustion of wood and paper and slightly more than 50% of particles generated by plastic combustion were ultrafine, which is consistent with the earlier findings (Baxter et al., 2010).

The natural decay of airborne particle concentration was found to be dependent on particle size. It is seen in Figure 12.3 that the natural decay was very slow for wood and paper combustion particles above 80 nm, and plastic combustion particles above 100 nm. The slower decay for larger particles can be explained by weakening diffusion as well as continuous coagulation (Kulkarni et al., 2011). The curves demonstrate a pronounced concentration decrease during approximately the first 50 min, which slowed down afterward. On average, approximately 40% of particles remained airborne after 90 min. This assured a sufficient number of particles available for counting in each nano-ID channel.

12.3.2 Half-Mask Elastomeric Respirator with P100 Filters

12.3.2.1 Respirator Donned on the Manikin (Unsealed, Non-Size-Selective Measurement)

As shown in Table 12.2, for the constant flow 30 L/min, the overall particle penetration was very high: average values were 43.97% ± 2.44% (wood aerosol), 48.37% ± 0.15% (paper aerosol), and 50.67% ± 0.61% (plastic aerosol). ANOVA revealed a statistically significant (*p*-value <0.05) effect of combustion material, but from the practical standpoint it does not play an important role since all measured penetration values fell between 40% and 52%. The important finding is that the obtained penetration level is over three orders of magnitude higher than the one expected based solely on the filter efficiency. Indeed, the respirator was equipped with a P100 filter that has a collection efficiency of 99.97% for the most penetrating particle size (MPPS) at a constant flow of 85 L/min, which corresponds to an overall penetration of $\leq$0.03% at 85 L/min and even lower at 30 L/min (no data are available for 135 L/min). This means that most of the penetrated particles entered through the face seal leakage; only one out of thousands of the penetrated particles entered through the filter medium. When testing with an unsealed respirator, a substantial gap (~1 mm) located around the nose of the manikin was observed, indicating a poor fit for the tested respirator

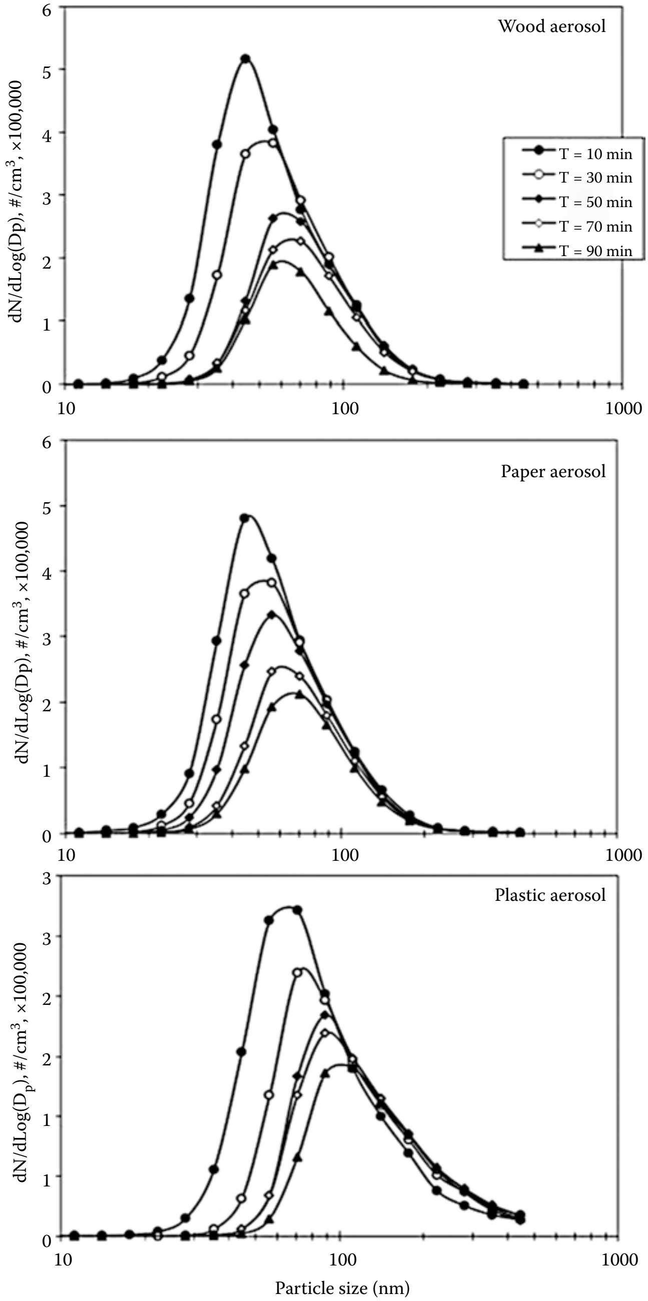

FIGURE 12.3
Particle size distributions of three combustion aerosols (wood, paper, and plastic) measured at 10, 30, 50, 70, and 90 min after the material burning stopped.

TABLE 12.2

Penetration Values for a Half-Mask Elastomeric Respirator

Materials	Flow Type[a], Flow Rate (L/min)	Penetration, % (Mean ± SD)			
		Unsealed	Nose-Only Sealed	Nose and Chin Sealed	Fully Sealed
Wood	Constant, 30	43.97 ± 2.44	1.19 ± 0.08	0.33 ± 0.02	0.000 ± 0.000
	Cyclic, 30	8.27 ± 0.25	0.18 ± 0.01	0.23 ± 0.01	0.001 ± 0.000
	Cyclic, 85	6.63 ± 0.25	0.29 ± 0.01	0.34 ± 0.01	0.002 ± 0.000
	Cyclic, 135	5.37 ± 0.29	0.48 ± 0.01	0.29 ± 0.02	0.011 ± 0.003
Paper	Constant, 30	48.37 ± 0.15	0.66 ± 0.19	0.28 ± 0.11	0.000 ± 0.000
	Cyclic, 30	11.3 ± 0.26	0.11 ± 0.01	0.21 ± 0.02	0.001 ± 0.000
	Cyclic, 85	8.10 ± 0.44	0.19 ± 0.00	0.36 ± 0.01	0.002 ± 0.000
	Cyclic, 135	5.83 ± 0.06	0.25 ± 0.01	0.28 ± 0.01	0.011 ± 0.003
Plastic	Constant, 30	50.67 ± 0.61	0.69 ± 0.12	0.14 ± 0.04	0.000 ± 0.000
	Cyclic, 30	11.4 ± 0.10	0.12 ± 0.01	0.25 ± 0.00	0.000 ± 0.000
	Cyclic, 85	8.23 ± 0.25	0.20 ± 0.01	0.35 ± 0.02	0.002 ± 0.000
	Cyclic, 135	6.1 ± 0.10	0.25 ± 0.01	0.28 ± 0.01	0.011 ± 0.001

[a] For cyclic flow regime, the number represents MIF.

donned on the manikin, which could result in unexpectedly high penetration values. This was likely caused by the fact that the manikin was made of hard plastic. Softer human skin would likely form a better seal, resulting in lower penetration values for the elastomeric half-mask respirator.

The total particle penetration results from two components: the filter penetration (P_F) at the corresponding flow through the filter (Q_F) and the leakage penetration (P_L) at the corresponding air flow (Q_L). It can be expressed as Equation 12.1

$$\begin{aligned} P &= \frac{C_{in}}{C_{out}} = \frac{N_{in}}{N_{out}} = \frac{N_F + N_L}{N_{out}} = \frac{N_F}{N_{out}} + \frac{N_L}{N_{out}} = \frac{P_F N_{out} \dfrac{Q_F}{Q}}{N_{out}} + \frac{P_L N_{out} \dfrac{Q_L}{Q}}{N_{out}} \\ &= P_F \frac{Q_F}{Q} + P_L \frac{Q_L}{Q} = P_F \frac{Q_F}{Q} + P_L \left(1 - \frac{Q_F}{Q}\right) \end{aligned} \tag{12.1}$$

where

N_{in}—Particle numbers inside the respirator

N_{out}—Particle number outside the respirator

N_F—Number of particle penetrating through the filters

N_L—Number of particles penetrating through the leakage

Q—Breathing flow = $Q_F + Q_L$

It is clear from Equation 12.1 how crucial it is to determine the relative contribution of the air flow through the filter to the total air flow. Therefore, a separate experiment was conducted to measure Q_F when the half-mask was donned on the manikin. A flow meter (Model: 4043, TSI Inc.) was placed between the filter and the respirator. Three breathing (constant) flows (30, 85, and 135 L/min) were selected. For each flow, the respirator was taken off from the manikin, and put back on. Then, the filter flow was recorded after each re-donning of the respirator. Seven replicates were performed for each flow (which makes the total number of runs equal to 21). It was determined that the fraction of the breathing flow entering through the filter (Q_F/Q) was 56.0% ± 7.2% at 30 L/min, 61.7% ± 4.4% at 85 L/min, and 61.0% ± 4.0% at 135 L/min. Given that P_F of a P100 filter is negligibly low (<0.03%) compared to P_L, and Q_F and Q_L are comparable (according to the above experimental data), Equation 12.1 can be simplified as Equation 12.2

$$P \approx P_L\left(1 - \frac{Q_F}{Q}\right) \tag{12.2}$$

The particle loss inside the gap (~1 mm) was estimated to be negligibly low according to a classic particle diffusion theory (Kulkarni et al., 2011). For these conditions, P_L is close to 100%, which allows further simplifying the equation for the overall particle penetration to Equation 12.3

$$P \approx 1 - \frac{Q_F}{Q} \tag{12.3}$$

According to this assessment, the overall penetration values are expected to be slightly below 50% at 30 L/min and about 40% at 85 and 135 L/min, which is in a reasonable agreement with the penetration values experimentally obtained for an unsealed half-mask tested against three combustion aerosols under constant flow of 30 L/min (listed in Table 12.2). However, Equation 12.3 is limited to constant flow only, and cannot be applied to cyclic flow conditions representing a much more complex two-direction flow regime.

In the cyclic flow tests, the penetration was 8.27% ± 0.25% for wood combustion aerosol with a MIF of 30 L/min which is approximately five-fold lower than the one obtained in the same experiment with constant flow (43.97% ± 2.44%). Similar results were observed for paper and plastic combustion aerosols. Overall, P_{cyclic}-values were approximately four to eight times lower than the corresponding $P_{constant}$-values. One reason for this difference is that with constant flow, aerosol particles continuously penetrate into the respirator (mostly through the leakage). However, under the cyclic flow regime, no particles enter during exhalation (half of the period). The return flow is particle-free since it is supplied back into the respirator through a

HEPA filter installed between the manikin and the breathing simulator. This time factor causes a two-fold decrease in aerosol concentration inside the respirator with cyclic breathing compared to constant flow, which explains a 50% drop in the measured penetration. In addition, the returning clean air flow dilutes the particle-contaminated air inside the respirator by a volumetric factor of two, thus further decreasing the aerosol concentration C_{in}. Consequently, it should be anticipated that P_{cyclic} is at least four times below the corresponding $P_{constant}$. This explanation is valid when the majority of particles detected inside the respirator penetrate directly through facepiece leaks (not the filter). The situation is different when the aerosol enters solely through the filter (see Table 12.2—fully sealed respirator). In addition, with cyclic flow, the relative contribution of air flow through the face seal leak and filter changes with time, which affects the difference between the penetration levels obtained in the two protocols (constant vs. cyclic flow). The large and consistent difference between $P_{constant}$ and P_{cyclic} found in this study points to a significant limitation of the existing respirator evaluation protocols that are based on the constant flow design.

As MIF of the cyclic flow increased, the particle penetration decreased. This was observed for all three combustion materials and was statistically significant (see Table 12.3). One possible explanation is changing leak size with increasing cyclic flows. Higher flows can generate higher negative pressures inside the respirator during breathing, which improves the sealing performance of the respirator. It should be stressed that P_{cyclic}-values that ranged from a low of 5.37% ± 0.29% (wood, 135 L/min) to a high of 11.4% ± 0.10% (plastic, 30 L/min) are still well above the expected penetration level of P100 filters ($<$0.03%). This suggests that face seal leakage was the primary penetration pathway for the unsealed half-mask respirator tested in this study.

The data obtained by He et al. (2013a) with the three tested combustion materials revealed similar trends, with paper and plastic producing slightly higher penetrations than wood (see Table 12.4). There was no statistically significant difference in penetration between paper and plastic combustion aerosols. As the quoted study was the first one of a kind dealing with combustion aerosols, no direct comparisons could be made with previous studies.

12.3.2.2 Respirator Donned on the Manikin (Unsealed, Size-Selective Measurement)

The size-selective particle penetration results for the unsealed half-mask are presented in Figure 12.4. The ANOVA testing revealed that both particle size and material type had strong significant effects ($p < 0.001$) on particle penetration. The penetration values ranged from 4% to 8% for wood aerosol, from 3% to 10% for paper aerosol, and from 3% to 16% for plastic aerosol. Plastic aerosol produced higher penetration values for particles between 100 and 200 nm as compared to wood and paper combustion aerosols. This finding

TABLE 12.3

ANOVA with Tukey's Range Test on the Effects of the Flow Rate Adjusted for Material (Half-Mask)

Tukey Grouping[a]	Mean Penetration[b] (%)	Flow Type Flow Rate (L/min)
Unsealed		
A	47.7	Constant, 30
B	10.3	Cyclic, 30
C	7.7	Cyclic, 85
D	5.8	Cyclic, 135
Nose-Only Sealed		
A	0.85	Constant, 30
B	0.33	Cyclic, 135
C	0.23	Cyclic, 85
C	0.14	Cyclic, 30
Nose and Chin Sealed		
A	0.35	Cyclic, 85
B	0.28	Cyclic, 135
B C	0.25	Constant, 30
C	0.23	Cyclic, 30
Fully Sealed		
A	0.011	Cyclic, 135
B	0.002	Cyclic, 85
B	0.000	Cyclic, 30
B	0.000	Constant, 30

[a] Means with the same letter are not significantly different (p-value >0.05).
[b] Calculated over all combustion materials.

is important in light of previously published evidence that combustion of plastic generates toxic particles that may be associated with human health effects (Linak et al., 1989; Wong et al., 2007).

For the plastic aerosol, the size of particles most readily penetrating through face seal leakage fell in a range of 120–140 nm for all three MIFs, whereas it is difficult to determine the MPPS for wood and paper aerosols as the penetration curves do not show clear peaks in the particle size range of 20–200 nm. Many previous studies on respirator filter efficiency have reported the MPPS for tested filters (Brown, 1993; Martin and Moyer, 2000; Grafe et al., 2001; Bałazy et al., 2006a; Eninger et al., 2008). However, there are very limited data available on the MPPS for respirator face seal leakage. Rengasamy and Eimer (2011) reported that the MPPS for a cylindered leak (<1.65 mm diameter) was approximately 50 nm. It is commonly assumed that size and location of face seal leakage are constantly changing during breathing, talking, and head/body movement (Myers et al., 1996), which contributes to additional

TABLE 12.4

ANOVA with Tukey's Range Test on the Effects of the Material Adjusted for Breathing Flow (Half-Mask)

Tukey Grouping[a]	Mean Penetration[b] (%)	Material
Unsealed		
A	19.1	Plastic
A	18.4	Paper
B	16.1	Wood
Nose-Only Sealed		
A	0.53	Wood
B	0.31	Plastic
B	0.30	Paper
Nose and Chin Sealed		
A	0.30	Wood
A B	0.28	Paper
B	0.26	Plastic
Fully Sealed		
A	0.003	Paper
A	0.003	Wood
A	0.003	Plastic

[a] Means with the same letter are not significantly different (p-value >0.05).

[b] Calculated over all breathing flow type and flow rate.

variability when trying to determine the MPPS. Additional challenge is that the MPPS can be affected by aerosol type as shown in this study.

An unsealed respirator involves two primary particle penetration pathways (filter medium and face seal leakage). While numerous studies have addressed the effect of breathing flow on the filter efficiency (e.g., increasing flow rate was shown to promote higher penetration of ultrafine particles due to diffusion) (Bałazy et al., 2006a,b; Eninger et al., 2008; Rengasamy and Eimer, 2011), it is less certain how the breathing flow affects face seal penetration. Interestingly, several published FFR studies have documented that face seal penetration decreased with increase in breathing flow when challenged with particles above 500 nm (Chen et al., 1990; Huang et al., 2007; Cho et al., 2010b). On the other hand, another FFR evaluation effort failed to observe significant increase or decrease in face seal penetration when increasing the breathing flow (Rengasamy and Eimer, 2011) for particles ranging from 8 to 400 nm. In He et al. (2013b) study, increasing flow seemed to reduce particle penetration through the face seal leakage, and such effect was most dominant for plastic aerosol and particle size of >100 nm. It is acknowledged that He et al. (2013b) study tested a different respirator (elastomeric half-mask)

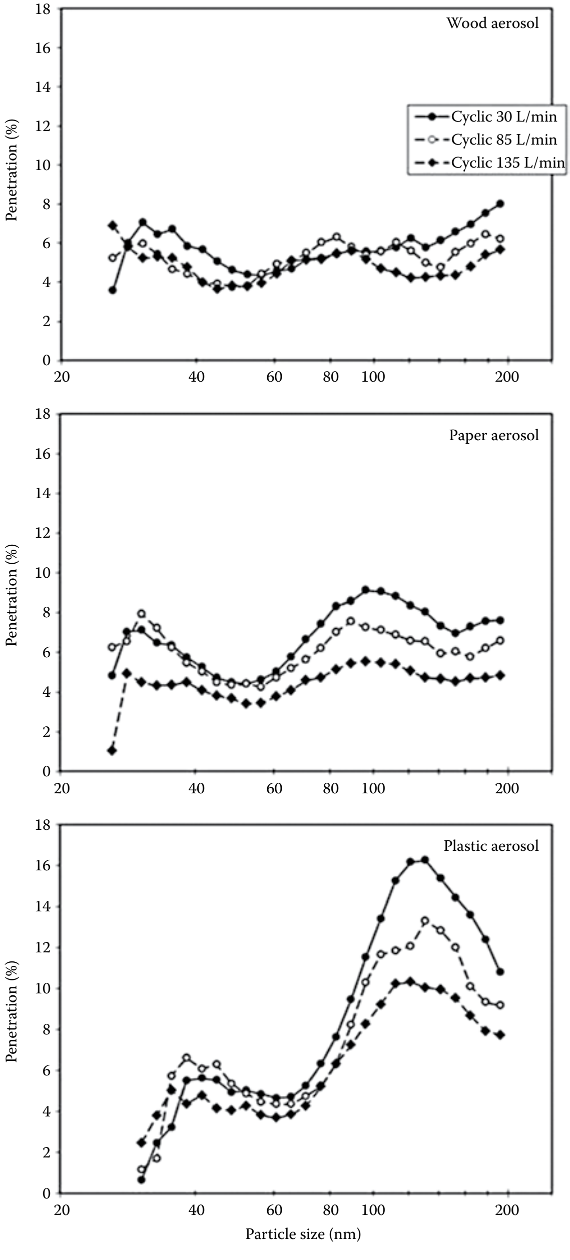

FIGURE 12.4
Penetration of wood, paper, and plastic combustion aerosols through an unsealed half-mask equipped with two P100 filters.

with different challenge aerosols compared to the three above-referenced reports (Chen et al., 1990; Huang et al., 2007; Cho et al., 2010b).

12.3.2.3 Respirator Partially Sealed on the Manikin (Nose-only Sealed and Nose and Chin Sealed, Non-Size-Selective Measurement)

As seen from Table 12.2, penetration values obtained under these two conditions were significantly lower than those determined for the unsealed respirator (see Table 12.5). In most cases, the decrease was almost two orders of magnitude. The data indicate that most of the leakage occurred around the manikin's nose.

There were no significant differences in penetration between the two partial sealing conditions labeled as "nose-only" and "nose and chin" regardless of the combustion material and the breathing air flow (see Table 12.5). This further suggests that sealing the nose area (rather than the chin area) reduced penetration on average from approximately 5%–11% (unsealed) to 0.11%–0.48% (nose-only sealed) for the cyclic flow regime, and from approximately 44%–51% (unsealed) to 0.66%–1.19% (nose-only sealed) for the constant flow regime. This finding is consistent with other studies (Oestenstad et al., 1992, 2010; Crutchfield et al., 1997) that suggest the nose is frequently the primary leak location.

Although partial sealing reduced the total particle penetration to values below 1%, these levels are still much higher than that for a P100 filter alone (<0.03% or =0.3%). Thus, although offering much greater protection against combustion particles, partial sealing still left a considerable opportunity for penetration through face seal leakages so that full advantage could not be taken of the highly efficient P100 filter deployed in a half-mask elastomeric respirator.

For nose-only sealed condition, He et al. (2013a) reported that penetration remained at the same level at 30 and 85 L/min but was significant higher at 135 L/min (see Table 12.3). For nose-chin sealed condition, there were significant differences between the outcome observed at three MIFs (30, 85, and

TABLE 12.5

ANOVA with Tukey's Range Test on the Effects of the Sealing Condition Adjusted for Material and Breathing Flow (Half-Mask)

Tukey Grouping[a]	Mean Penetration[b] (%)	Sealing Condition
A	17.9	Unsealed
B	0.38	Nose-only sealed
B	0.28	Nose and chin sealed
C	0.003	Fully sealed

[a] Means with the same letter are not significantly different (*p*-value >0.05).

[b] Calculated over all combustion material and breathing flow.

135 L/min). Compared to the unsealed condition, the P_{cyclic}-values obtained for the two partial sealing conditions were 10–100 times lower as determined at the same MIF. The results also show that increasing the flow does not always reduce the face seal penetration. In another study, Cho et al. (2010b) reported that face seal penetration was reduced significantly (p-value <0.001) with increasing breathing flow. A different type of respirator (N95 FFR partially sealed on a manikin) tested in the quoted study may exhibit face seal leaks of different sizes, which could cause the disagreement between the two studies.

Penetration values were higher for wood combustion aerosol as compared to paper and plastic combustion aerosols in both "nose-only" and "nose and chin" sealed conditions (see Table 12.4). In contrast, for an unsealed respirator, the plastic combustion aerosol exhibited the highest penetration. The finding suggests that a better sealing may produce a different effect on the respiratory protection level for different aerosols, for example, be more beneficial for protecting against plastic combustion particles than against other materials. This seems to have a significant practical relevance, especially given that burning plastic generates more toxic combustion particles making their elimination by a respirator particularly important.

12.3.2.4 Respirator Partially Sealed on the Manikin (Nose-Only Sealed, Size-Selective Measurement)

As there was no significant difference between two conditions "nose-only sealed" and "nose and chin sealed" in the non-size-selective study for the same half-mask respirator, only one partially sealed condition—a nose area seal—was chosen for this study (the length of the seal was 12.7 cm, which is approximately 30% of the 40.6 cm total respirator sealing length). Figure 12.5 presents the particle penetration data for a partially sealed half-mask with two P100 filters, which was tested at three MIFs (30, 85, and 135 L/min) while exposed to three combustion aerosols (wood, paper, and plastic). Data analysis revealed that combustion material and particle size had a significant effect on penetration values ($p < 0.001$). For all three materials, the highest particle penetration values occurred at 85 L/min throughout the entire tested particle size range (20–200 nm) except for the first channel; the 135 L/min flow generated the second highest penetration levels followed by 30 L/min. All penetration values obtained with the three combustion aerosols were approximately between 0.05% and 0.7% except a few points obtained for smaller particles at 30 L/min. The insufficient number of particles detected by the nanoparticle spectrometer ($C_{out} < 1000$ particles/channel, $C_{in} < 1$ particle/channel) prevented us from reporting penetration values for plastic particles between 20 and approximately 30 nm (see Figure 12.3, plastic aerosol).

The penetration curves obtained for wood and paper combustion aerosols are seen to be of similar shapes. While not perfectly monotonic, the curves

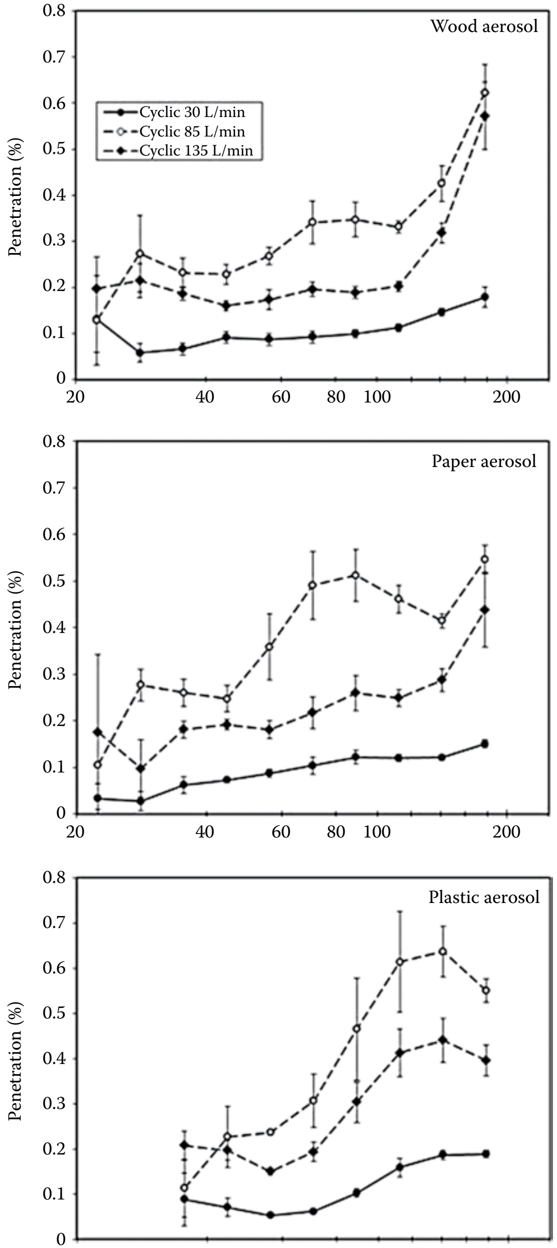

FIGURE 12.5
Penetration of wood, paper, and plastic combustion aerosols through a partially sealed (nose area) half-mask equipped with two P100 filters.

show an overall increase of penetration with increasing particle size. For plastic combustion particles, the curves are slightly different from those found for wood and paper aerosols with the penetration reaching the maximum approximately at 120–160 nm at 85 and 135 L/min. One possible reason is that wood and paper combustion aerosol particles are expected to have similar physical and chemical properties while the particles originated by burning plastic, a synthetic material, may differ in composition and physical characteristics such as a charge, shape, and density. It is worth mentioning that, although effects associated with electrical charges on particles as well as on respirator and manikin surfaces fell outside of the scope of this study, electric forces may have a major contribution to the differences associated with combustion materials. It is also to be noted that the measurement of particles in this study was based on their electrical mobility (not on aerodynamic diameters), and there are no data, to our knowledge, that would allow establishing a relationship between the two, at least, for the challenge aerosol. All these factors may explain the material-associated differences and similarities observed in our experiments.

The order of curves in Figure 12.5 was somewhat unexpected: at the same particle size the penetration increased as the MIF increased from 30 to 85 L/min but then decreased as the flow continued rising from 85 to 135 L/min at MIF. In order to identify the flow rate(s) associated with the maximum particle penetration, four more cyclic flows (50, 70, 100, and 120 L/min) were added to the testing program for the partially sealed half-mask. This additional experiment was conducted using the plastic combustion aerosol only. It is believed that the finding would have higher practical significance because the plastic aerosol is comparatively more toxic and more health-relevant than the ones produced by burning wood or paper (UL, 2010). Thus, seven flows (30, 50, 70, 85, 100, 120, and 135 L/min) were tested at the same manikin breathing frequency (25 breaths/min) with four replicates for each flow. The experimental results are presented in Figure 12.6. The penetration values are shown for particle sizes of and above of 30 nm (as mentioned earlier, the count of plastic combustion particles below 30 nm was insufficient).

Firstly, the curves (upper section of Figure 12.6) corresponding to seven different MIFs are similarly non-monotonic. Although the trend is not completely clear for particle diameters up to 40–50 nm, all the curves indicated that penetration increased with increasing particle size up to approximately 100–140 nm (depending on the flow rate) and then decreased for larger particles. The flow rate of 85 L/min indeed appeared to be the one producing the highest penetration values when particle size was >40 nm. The flow rate of 100 L/min produced the second highest penetration (the values are approximately the same compared to 85 L/min in the particle size range of 80–100 nm). Further increase in flow rate resulted in decrease in penetration. The lowest penetration values were detected at the lowest tested MIF (30 L/min). The following explanations are offered to address the flow effect:

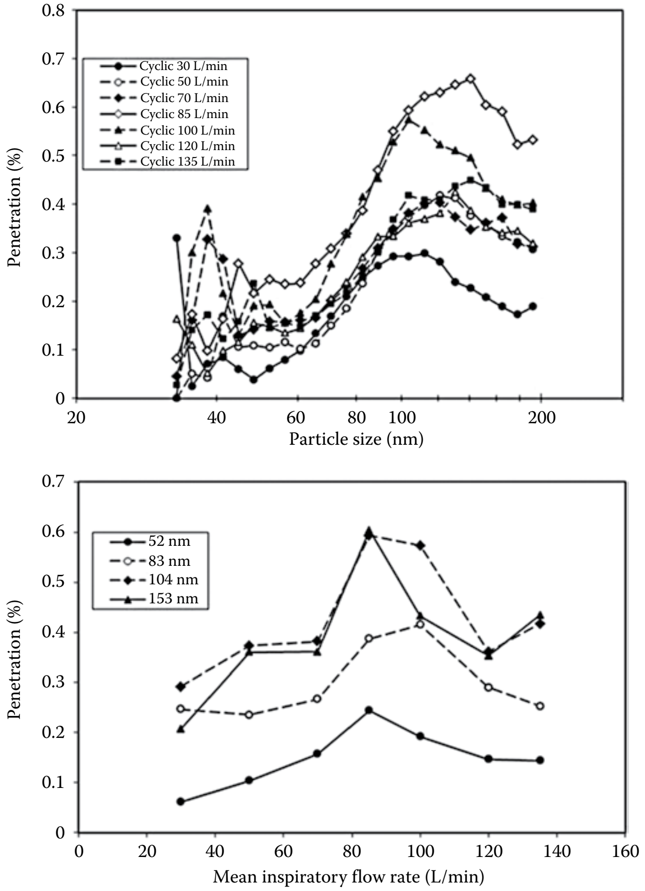

FIGURE 12.6
Penetration of plastic combustion particles through a partially sealed (nose area) half-mask equipped with two P100 filters: dependence on particle size for fixed MIFs (upper figure), and dependence on the MIF for fixed particle sizes (lower figure).

as the breathing flow increased from 30 to 85 L/min, more combustion particles were brought into the respirator cavity (greater penetration) while the outside concentration remained unchanged. However, it is anticipated that at higher flows (>85 L/min) the negative pressure inside the respirator during inhalation became sufficiently high to suck the respirator toward the face of the manikin and consequently reduce face seal leak size. In turn, a smaller leak could correspond to a lower relative contribution of the total air flow entering the facepiece, resulting in penetration of fewer particles. During exhalation, exhaled air is released primarily through the exhalation valve (rather than the face seal leakage or filters) of the half-mask respirator so that a higher flow should not substantially increase the leak size during exhalation.

Secondly, the lower section of Figure 12.6 shows the particle penetration as a function of MIF at four particle sizes (52, 83, 104, and 153 nm) that were selected to fairly represent the entire scan range. This figure conveys that the particle penetration was largely dependent on the cyclic breathing flow, with the highest penetration values occurring at the MIF = 85 L/min. As particle size increased from 52 to 104 nm, the penetration values showed a clear increasing trend regardless of the flow rate. However, penetration values obtained at the larger particle size (153 nm) were close to or higher than those acquired at 104 nm (depending on the flow rate). This indicates that the MPPS for this partially sealed half-mask (nose area only) was within a size range of approximately 100–160 nm when challenged to plastic combustion aerosols.

12.3.2.5 Respirator Fully Sealed on the Manikin

The fully sealed respirator prevented particles from penetrating through the face seal leakage. Therefore, total particle penetration equals filter penetration ($P = P_{filter}$) assuming no penetration through the exhalation valve. A separate experiment was conducted to test the assumption that the exhalation valve operated properly, thus introducing no additional pathway for particles to penetrate inside the respirator. In this experiment, the same respirator with a functional exhalation valve was compared to a sealed valve. The penetration was determined at a constant flow of 135 L/min as well as at a cyclic flow of MIF = 135 L/min. For either flow conditions, no significant difference in the penetration values was found. The results confirmed that the exhalation valve had no influence on particle penetration, which supports the fundamental postulate of our study design of only two particle penetration pathways (filter and face seal).

For a fully sealed half-mask respirator, the total penetration should be equal to the filter penetration, which is supposed to be below 0.03% at 85 L/min for a NIOSH-certified P100 filter. The tests revealed no particle penetration at constant flow rate of 30 L/min. For low to moderate cyclic flows, filter penetration was 0.002% or below. At the highest flow (MIF = 135 L/min), the average penetration was around 0.011%. It is noted these results were obtained in the non-size-selective study, which reflects the total particle count regardless of the particle size.

The filter penetration generally depends on the particle size reaching the highest value for the MPPS. Figure 12.7 presents the size-selective particle penetration values for the fully sealed half-mask respirator equipped with two P100 filters challenged with particles aerosolized by wood combustion. A study conducted with an identical fully sealed half-mask indicated that the effect of combustion material on the particle penetration was not significant (p-value >0.05); therefore, only one combustion material (wood) was tested here. Except for a few points obtained at 135 L/min, all the other values were below 0.005% regardless of the particle size and flow rate. The two peak points that occurred at the lower (~30 nm) and higher (~180 nm) sizes could

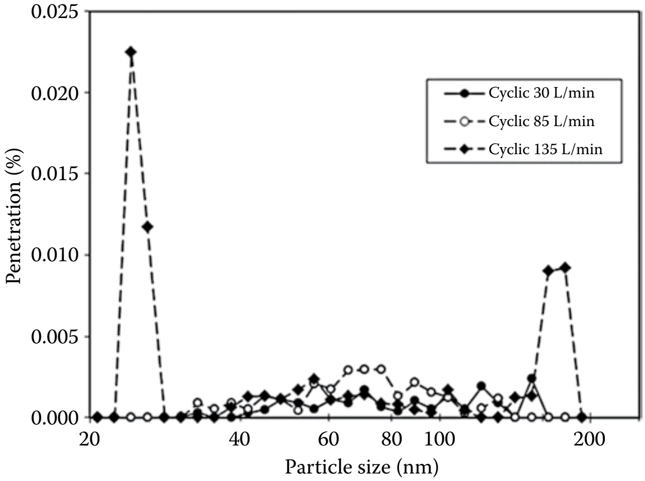

FIGURE 12.7
Penetration of wood combustion aerosol through a fully sealed half-mask equipped with two P100 filters.

be outliers as there were not sufficient number of particles ($C_{out} < 10{,}000$ particles/channel, $C_{in} < 1$ particle/channel) generated at those two sizes especially after the 90 min measurement (see Figure 12.3, wood aerosol). However, even if these two peaks were considered as valid data points, the maximum filter penetration would still fall below 0.025% (see Figure 12.7). Overall, the results summarized above demonstrate that the tested P100 filters exhibited the efficiency levels exceeding the NIOSH certification requirement ($P \leq 0.03\%$). This finding is in agreement with the data obtained using a non-particle size-selective aerosol measurement technique (He et al., 2013b). Several other studies also reported similarly low particle penetration for P100 filters (Eshbaugh et al., 2008; Rengasamy and Eimer, 2011).

12.3.3 Full Facepiece Elastomeric Respirator with P100 Filters

12.3.3.1 Respirator Donned on the Manikin (Unsealed, Non-Size-Selective Measurement)

As seen from Table 12.6, penetration values for the unsealed condition were extremely low for all flows and materials. At 30 L/min, $P_{constant}$ ranged from 0.017% (wood) to 0.035% (plastic). The values of P_{cyclic} were even lower: from 0.003% for MIF = 30 L/min (all three combustion materials) to 0.025% (135 L/min, plastic). These levels were approximately three orders of magnitude lower than the penetrations obtained for the half-mask elastomeric respirator. The difference is likely associated with the leak size. The nose has been identified as the primary leak location for half-mask respirators (see the half-mask section above), whereas full facepiece does not have a nose leak

TABLE 12.6

Penetration Values for a Full Facepiece Elastomeric Respirator

Materials	Flow Type Flow Rate (L/min)	Penetration, % (Mean ± SD) Unsealed	Fully Sealed
Wood	Constant, 30	0.017 ± 0.002	0.001 ± 0.000
	Cyclic, 30	0.003 ± 0.001	0.001 ± 0.000
	Cyclic, 85	0.010 ± 0.001	0.003 ± 0.000
	Cyclic, 135	0.019 ± 0.001	0.013 ± 0.002
Paper	Constant, 30	0.024 ± 0.000	0.000 ± 0.000
	Cyclic, 30	0.003 ± 0.001	0.000 ± 0.000
	Cyclic, 85	0.008 ± 0.000	0.002 ± 0.000
	Cyclic, 135	0.016 ± 0.001	0.010 ± 0.000
Plastic	Constant, 30	0.035 ± 0.001	0.001 ± 0.000
	Cyclic, 30	0.003 ± 0.001	0.001 ± 0.000
	Cyclic, 85	0.012 ± 0.001	0.002 ± 0.000
	Cyclic, 135	0.025 ± 0.002	0.011 ± 0.000

(thus penetration dramatically reduced). The difference between the cyclic and constant flow regimes for the full facepiece was not as big as the one observed with the half-mask. Again, this also can be explained by the leak size. As the full facepiece does not have nose leaks, it is more comparable to a partially sealed half-mask rather than a fully sealed half-mask.

The lowest MIF (30 L/min) produced the lowest penetration; as the flow increased, the penetration increased (p-value < 0.05). Since the penetration values were so low and closer to those expected from the filter material, one would suggest that the role of face seal leakage pathway is not as great for the full facepiece elastomeric respirator if compared to the half-mask, and the particle deposition on the filter governs the process, at least to a significant extent. For ultrafine particles used in this study, the primary filtration mechanism is diffusion. As the flow increases, the residence time decreases, and the diffusion becomes less effective. This explains the experimentally observed effect of MIF on the particle penetration.

12.3.3.2 Respirator Fully Sealed on the Manikin

The data obtained with the fully sealed full facepiece were similar to those obtained with the fully sealed half-mask. This is understandable because testing of a fully sealed respirator (both half and full facepiece) is essentially equivalent to examining the performance of the respirator filter (with an exhalation valve attached). As the same type of filter was used for the half and full facepiece respirators, there was no significant difference in the filter efficiency. The results are consistent with the fact that the efficiency of a P100 filter is 0.03% or below at 85 L/min.

12.4 Conclusions

Factors such as face seal leakage, breathing flow type and rate, combustion material, and particle size have significant impact on the performance of elastomeric respirators (half-mask and full facepiece). The total penetration through the fully sealed half and full facepiece respirators evaluated by He et al. (2013a,b) does not exceed the NIOSH certification level established for P100 respirator filters (<0.03%). Increasing leak size increases total penetration. When testing the partially sealed half-mask, the highest penetration is detected at 180 nm for wood and paper combustion aerosols, and at around 120–160 nm for plastic aerosol. Effects of combustion material and breathing flow are significant and heavily dependent on the sealing condition. The results presented by He et al. (2013a,b) suggest that eliminating or minimizing the face seal leakage is the key aspect for improving the efficiency of elastomeric respirators.

A significant difference in penetration occurs between cyclic and constant flow; however, this difference is mainly observed for the unsealed half-mask. For the half-mask (fully sealed) and full facepiece (unsealed or fully sealed), the penetration remains the same when challenged with three different combustion aerosols (wood, paper, and plastic). While under sealing conditions such as "nose-only", "nose and chin", and "unsealed", the combustion material does show a significant effect on the total penetration for the half-mask. According to He et al. (2013a) this effect was not consistent—the plastic aerosol produced the highest penetration under the unsealed condition, whereas for the two partial sealing conditions the wood aerosol was associated with the highest penetrations.

Material type is another significant factor. For the unsealed half-mask challenged with the plastic combustion aerosol, higher penetration values were reported observed as compared to the wood and paper aerosols for particles >100 nm (He et al., 2013b).

The above-described studies provide meaningful information related to the NIOSH respirator testing program in accordance with Title 42 of the Code of Federal Regulations, Part 84. The results indicate that the efficiency of a P100 respirator filter is not significantly influenced by the challenge aerosol and the flow type (constant vs. cyclic). This supports the approach implemented in the current NIOSH respirator testing of P100 filters that utilizes a non-combustion challenge aerosol and constant air flow. However, the NIOSH TIL test assumes that the result is independent of the type of the tested aerosol, while the tests by He et al. (2013a,b) revealed that the challenge aerosol significantly affects the particle penetration through unsealed and partially sealed half-mask elastomeric respirators. The differences between the currently utilized challenge(s) and actual combustion aerosols are concerned with the particle shape, density, electric charge, and possibly other properties. It is concluded that the findings generated by the presently adopted TIL test protocol (utilizing ambient or NaCl model aerosols) may have limitations in predicting protection levels offered by half-mask elastomeric respirators.

One major limitation of the study presented in this chapter is that it utilized a hard plastic manikin headform, which was not fully capable of mimicking the texture and softness of human skin. This may potentially create larger leaks for equivalent strap tension. An advanced headform covered with soft skin-like material may be considered as an appropriate alternative in future studies.

Acknowledgment

Parts of the text reported in this chapter are reprinted with permission from the following publications:

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13

Impact of Facial Leakage on Respirator Efficiency: Recent Developments

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13.1 Introduction

Various types of respiratory protective devices are deployed to reduce inhalation aerosol exposure. The performance of respirators has been evaluated in many studies using different challenge aerosols (e.g., Brosseau et al., 1990, 1997; Chen et al., 1990; Chen and Willeke, 1992; Qian et al., 1997; Bałazy et al., 2006a,b; Eninger et al., 2008; Lee et al., 2008; Shaffer and Rengasamy, 2009; Cho et al., 2010a,b; Rengasamy and Eimer, 2011; He et al., 2013a,b,c,d,e,f; Gao et al., 2015, 2016a,b,c).

The current NIOSH certification of respirators conducted according Title 42 of the U.S. Code of Federal Regulations (Federal Register, 1995) is based on evaluation of the efficiency of a respirator filter medium. For example, a filtering facepiece respirator (FFR) receives an N95 certification if its filter exhibits an aerosol particle collection of at least 95%, which corresponds to a particle penetration of 5% or less. While capable of quantifying the penetration, the testing procedure solely evaluates the filter efficiency but does not account for faceseal leaks, although the latter represent an important pathway for particles entering the respirator (Coffey et al., 1998; Zhuang et al., 1998; Grinshpun et al., 2009; Cho et al., 2010b).

When wearing a respirator is required, the wearer must pass a fit test before entering the workplace. The fit test is designed to measure the total aerosol penetration through both pathways, the filter and the faceseal leaks (referred to as a total inward leakage [TIL]). There is no standard respirator testing protocol capable of quantitatively differentiating between the two pathways under actual breathing conditions. Several earlier studies attempted to assess the relative contributions of the two pathways. These include earlier manikin-based investigations of Chen and Willeke (1992) and Chen et al. (1990) who tested penetration for particles of 0.5–5 μm; however, their experiments were performed under constant-flow conditions and involved artificially created faceseal leaks.

Surgical masks that are not subjected to NIOSH filter certification testing or fit testing exhibit a very low aerosol collection efficiency primarily due to a poor seal which creates substantial faceseal leakage. It is acknowledged that surgical masks have not been initially developed to protect a wearer (the aim was to protect others from the aerosol particles exhaled by the wearer). While this fact as well as the low protection provided by surgical masks has been overwhelmingly recognized in the literature, these devices are widely used in health care environments.

13.2 Accounting for Penetration Pathways

Grinshpun et al. (2009) introduced a novel approach that allowed differentiating the contributions of the two penetration pathways for particles in the size range of 0.03–1 μm under actual breathing conditions. One widely used N95 FFR and one conventional surgical mask were tested on 25 subjects matching the NIOSH bivariate fit testing panel. The subjects performed conventional fit test exercises. In addition, the subjects' breathing patterns were recorded using the breathing recording and simulation system (BRSS, Koken Ltd., Tokyo, Japan). Subsequently, the respirator and mask were tested with breathing manikins that precisely simulated prerecorded breathing patterns. The human subject testing allowed determination of total penetration through the filter media and the faceseal leakage ($P_{\text{filter+leakage}}$), while filter penetration (P_{filter}) was obtained from the manikin tests with the respirator/mask perfectly sealed to the manikin's face (i.e., zero faceseal leakage). For each recorded breathing pattern, the subject-generated penetration values were compared to those obtained with the breathing manikin operating under the same (recorded and reproduced) pattern. This allowed calculating the "faceseal leakage-to-filter" (FLTF) ratio for different particle sizes and breathing patterns as follows:

$$\text{FLTF} = \frac{\text{Particle flux through the faceseal leakage}}{\text{Particle flux through the filter medium}}$$

This parameter quantifies the relative contribution of each of the two particle penetration pathways. Overall, 5250 particle size- and exercise-specific penetration values were determined in the Grinshpun et al. (2009) study. For each value, the FLTF ratio was calculated to quantify the relative contributions of the two penetration pathways. It was found that the number of particles penetrating through the faceseal leakage of the tested respirator/mask far exceeded the number of those penetrating through the filter medium. For the N95 respirator, the excess was (on average) by an order of magnitude and significantly increased with an increase in particle size ($p < 0.001$): approximately 7 fold greater for 0.04 μm, approximately 10-fold for 0.1 μm, and approximately 20-fold for 1 μm. For the surgical mask, the FLTF ratio ranged from 4.8 to 5.8 and was not significantly affected by the particle size for the tested submicrometer fraction. The data are presented in Figure 13.1.

It is to be noted that the particle sizes examined by Grinshpun et al. (2009) represent numerous occupational aerosols, including the viral and bacterial particles that are of special concern in the health care industry and biodefense. The quoted study demonstrated that facial/body movement had a pronounced effect on the relative contribution of the two penetration pathways. Breathing intensity and facial dimensions were shown to have some (although limited) influence.

Following the experimental finding described above, an effort was made to develop a theoretical model describing the penetration of aerosol particles inside an FFR by two routes—the filer and faceseal leakage (Mukhametzanov et al., 2016; Zaripov et al., 2016). The model involved a spherical porous layer representing a filter and an annular peripheral opening representing a faceseal leakage. The theory utilized a two-dimensional (2D) laminar incompressible flow in a free space and porous zones that were numerically characterized using a computational fluid dynamic code FLUENT. Following the model validation, the efficiency of an N95 FFR with an annular faceseal leakage opening was investigated as a function of the inhalation flow rate, particle size, and the ratio of the leak-to-filter areas. It was found—for two inhalation flow rates ($Q_i = 30$ and 85 L min^{-1}) and three particle diameters ($d_p = 50$ nm, 100 nm, and 1 μm)—that once the faceseal leakage area exceeded 0.1% of the total surface of an N95 facepiece, the respirator was unable to offer 95% protection, the minimum level that should be provided by its filter. It was demonstrated that under certain leakage conditions (partially determined by the inhalation flow rate), the respirator protection level becomes independent of the particle size; furthermore, it is not anymore affected by the efficiency of its filter and is only influenced by the size of the faceseal leakage (Mukhametzanov et al., 2016).

Similar conclusions with respect to the relative contribution of a faceseal leakage to the TIL have been drawn by He et al. (2013c,e) for elastomeric respirators. The data obtained for a half-mask and full face mask respirators are presented in detail in Chapter 12 of this book.

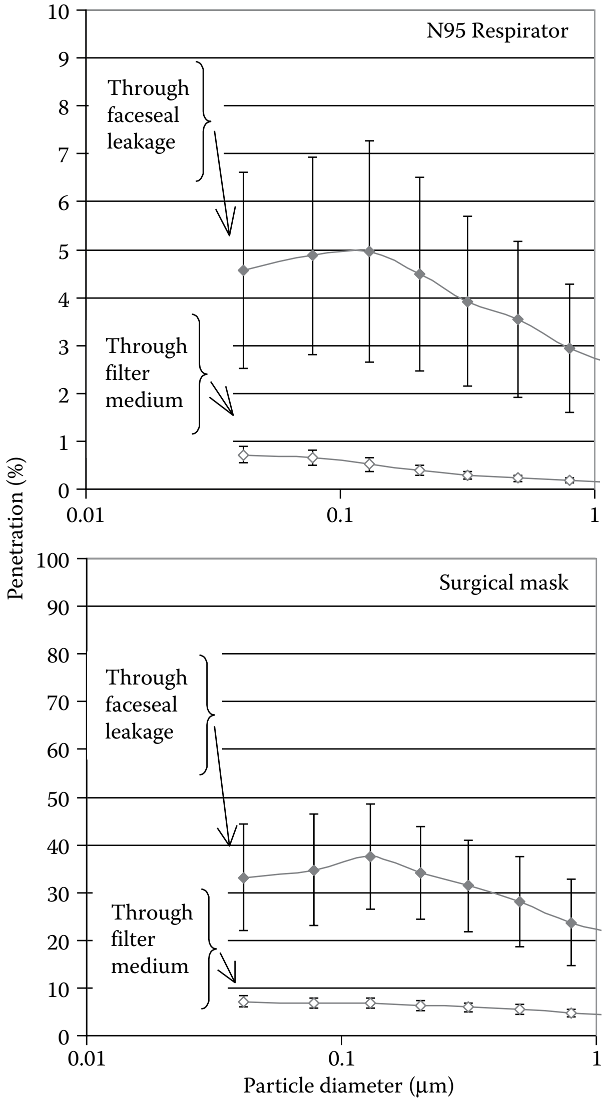

FIGURE 13.1
The panel-integrated particle penetration through the N95 FFR and the surgical mask as a function of particle size. Each point represents the average value and the standard deviation of 75 observations (25 subjects ×3 replicates). (Adapted from Grinshpun S.A. et al., 2009. *Journal of Occupational and Environmental Hygiene* 6(10): 593–603.)

13.3 Faceseal Leakage Implications on Respirator Development

Grinshpun et al. (2009) suggested—and it was echoed by the quoted follow-up experimental and theoretical investigations—that since most of the penetrated particles entered through the faceseal, the priority in respirator/mask development should be shifted from improving the efficiency of the filter medium to establishing a better fit that would eliminate or minimize faceseal leakage.

Several attempts have been made over the past decade toward faceseal leak reduction, primarily for disposable FFRs such as N95, N99, N100, P100, and alike. For instance, a novel FitSeal adhesion technology was introduced by Wein Products (Los Angeles, CA) and FaceSeal Technologies (Toronto, Canada). The developers applied an adhesive to a peripheral area of a disposable respirator, thus establishing a barrier between the respirator and face surface (Grinshpun et al., 2007; Lantos et al., 2009). Prototypes of Strapless Adhesion Face-sealed Mask utilizing this technology were extensively evaluated in the laboratory and in the field (Grinshpun et al., 2007, 2010, 2011) and shown to have a good potential for improvement of the FFRs′ protection level. An alternative approach to enhancing the faceseal was proposed by Technova Corporation (Lansing, MI). In this development, a polymeric micro-patterned adhesive material was applied along a peripheral area of an elastomeric half-mask respirator. The concept and prototype that utilized this approach were evaluated by fit testing 25 subjects representing the NIOSH bivariate panel. The idea showed promise for enhancing performance of elastomeric respirators, especially for wearers with challenging facial conditions, for example, poorly shaved individuals (He et al., 2013a).

The most recent development targeting the respirator faceseal leakage was initiated in 2014–2015 with the new face seal design, which creates a tight faceseal made of ethylene vinyl acetate foam affixed to the inner perimeter of the respirator, replacing the stock face seal (Koehler, 2015). The face seal design geometry was developed based on an anatomic analysis that revealed three zones on a human face where the most substantial leaks have been shown to occur. The inner perimeter of the first respirator prototype was designed to address these zones. The new approach was applied to wearers exposed to surgical smoke. Surgical smoke is an aerosol hazard unique to surgical operating rooms (ORs). Its source is an electrocautery procedure used in virtually all standard surgical facilities as a means of performing surgical dissection of various tissues. During electrocautery, an electrical current is passed through a resistant metal wire electrode, and the heated electrode is applied to the tissue for dissection or hemostasis (Pollock, 2008). Given the positioning of surgical personnel over and around the surgical patient, surgical smoke is often directly in the path of their respiratory field. The Occupational Safety and Health Administration

(OSHA) estimates that 500,000 workers are exposed to laser and electrocautery smoke in the United States each year (OSHA, 2007). The respiratory protective devices used in ORs are often inefficient against surgical smoke. The face seal proof-of-concept pilot study (Koehler et al., 2014) was conducted with two N100 FFRs, which were modified by affixing 1/4 and 3/8 inch thick ethylene vinyl acetate foam material to the inside periphery of the respirator's shell. Heating of the material was considered as an optional feature. The performance data were collected through quantitative fit testing followed by a workplace protection factor (WPF) measurement performed in a hospital OR, where electrocautery smoke was generated using standard surgical instruments. The fit factor and WPF data were compared with those obtained from two commercially available N100 FFRs. The results of this pilot study suggested that the new design offered considerable advancement in protecting wearers against aerosol hazards, particularly against surgical smoke in ORs. A follow-up study by Gao et al. (2016b) was conducted with two surgical masks, two N95 surgical mask respirators, and two N100 FFRs, worn by 10 subjects exposed to surgical smoke in a room-size exposure chamber. One N100 FFR was modified using the Koehler's face seal design. The smoke was generated by performing an electrocautery dissection on a section of animal muscle tissue mimicking a conventional surgical procedure. The data collected by Gao et al. (2016b) on the simulated WPF (SWPF) showed that conventional surgical masks provided essentially no protection with a geometric mean of SWPF <2, and the two tested N95 FFRs (both used in ORs) produced the SWPF geometric means of 208 and 263. In the meantime, the geometric mean SWPF of the commercial N100 FFR was 1089 while the respirator modified with the face seal offered a twice greater protection level against surgical smoke. Finally, the latest studies by Grinshpun et al. (2016) and Elmashae et al. (2017) confirmed that the new Face Seal Design has a very good potential for implementation in N95 FFRs used in health care environments.

13.4 Summary

In summary, faceseal leakage has a major impact on the protection level provided by respirators. The leakage-related contribution to the particle penetration inside a respiratory protective device has been proven and quantitatively characterized through several peer-reviewed studies involving respirators of different types exposed to various aerosol challenges under laboratory and field conditions. Several recent original developments utilizing faceseal enhancing technologies have shown a very good prospective for reducing the leakage and consequently achieving a significantly improved respirator performance.

Acknowledgment

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- Gao S., Koehler R.H., Yermakov M., Grinshpun S.A. 2016. Performance of facepiece respirators and surgical masks against surgical smoke: Workplace protection factor study. *Annals of Occupational Hygiene*; 60(5): 608–618.
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Section IV

Respiratory Protection for Industry

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14

Respiratory Protection against Isocyanate Exposures

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14.1 Overview

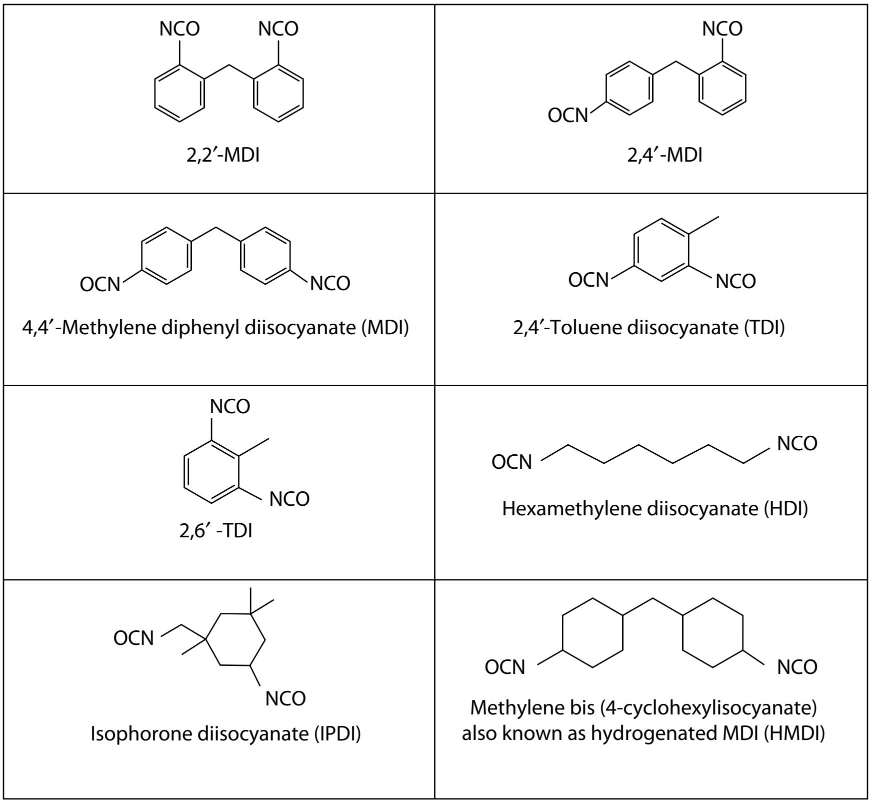
14.1.1 Isocyanate Structures

Isocyanates are a group of highly reactive, low-molecular-weight organic compounds that contain the functional group (–N=C=O) (Franklin et al. 2016). An isocyanate is a chemical that contains at least one isocyanate functional group in its chemical structure. The isocyanate functional group contains an atom of nitrogen and an atom of oxygen that both are linked with the atom of carbon with a double covalent bond. Isocyanates that have two isocyanate groups are called diisocyanates (3M 2017). A single molecule with one or two functional groups is called a monomer. Two or three molecules cross-linked together are called dimers (biuret) and trimers or prepolymers. More than three diisocyanate monomers cross-linked together are called polymers or polyisocyanates which are manufactured for reactions with polyols (an alcohol containing multiple hydroxyl groups) in the production of polyurethanes (a polymer composed of organic units joined by carbamate links which are mostly thermosetting polymers that do not melt). Prepolymers and polymers are also called oligomers. The most widely used compounds are diisocyanates, which contain two isocyanate groups, and polyisocyanates, which are usually derived from diisocyanates and may contain several isocyanate groups (American Chemistry Council 2017).

Isocyanates are classified into aliphatic and aromatic types based on their chemical structures. Aliphatic isocyanates can be cyclic and saturated or unsaturated, but do not contain a stable ring of benzene. Aromatic isocyanates are cyclic, planar molecule with a ring of resonance bonds that exhibit more stability than other geometric or connective arrangements with the same set of atoms. Commonly used aliphatic isocyanates include hexamethylene diisocyanate (HDI), isophorone diisocyanate (IPDI), and methylene bis-cyclohexylisocyanate (HMDI) (hydrogenated MDI). Commonly used aromatic isocyanates include toluene diisocyanate (TDI), methylene diphenylmethane diisocyanate (MDI), and naphthalene diisocyanate (NDI). The chemical structures of these commonly used isocyanates and their isomers are shown in Figure 14.1.

14.1.2 Isocyanate Chemical and Physical Properties

MDI ($C_{15}H_{10}N_2O_2$) has three isomers which vary by the positions of the isocyanate groups around the rings: 2,2′-MDI, 2,4′-MDI, and 4,4′-MDI. The 4,4′ isomer is most widely used. MDI has a very low vapor pressure at 0.000005 mmHg at 20°C that reduces its inhalation hazard. MDI is a white or pale yellow solid. TDI ($C_9H_6N_2O_2$) has six possible isomers, but two of them are most important: 2,4-TDI and 2,6-TDI. Commercial-grade TDI (which represents more than 95% of TDI industrial usage) is an 80:20 mixture of the two



2,2′-MDI

2,4′-MDI

4,4′-Methylene diphenyl diisocyanate (MDI)

2,4′-Toluene diisocyanate (TDI)

2,6′ -TDI

Hexamethylene diisocyanate (HDI)

Isophorone diisocyanate (IPDI)

Methylene bis (4-cyclohexylisocyanate)
also known as hydrogenated MDI (HMDI)

FIGURE 14.1
Chemical structures of commonly used isocyanates. (Adapted from Franklin G et al. *Environmental Health Insights* 2016;10:175–190. With permission.)

chemical isomers 2,4- and 2,6-TDI. TDI is more volatile with a vapor pressure at 0.01 mmHg at 25°C which makes it more hazardous. TDI is a colorless-to-amber liquid with a sharp and pungent odor. HDI ($C_8H_{12}N_2O_2$) has no isomers. Its vapor pressure is 0.05 mmHg at 25°C which makes it more hazardous than MDI but less than TDI. It is a colorless liquid with a sharp and pungent odor.

14.1.3 Isocyanate Production

Isocyanates are produced by treating an amine with phosgene in the liquid phase or in the gas phase: $RNH_2 + COCl_2 \rightarrow RNCO + 2HCl$. The first step of the production of MDI is the reaction of aniline and formaldehyde, using hydrochloric acid as a catalyst to produce a diamine precursor under the chemical formulation: $2C_6H_5NH_2 + CH_2O \rightarrow CH_2(C_6H_4NH_2)_2 + H_2O$. Then, these diamines are treated with phosgene to form an MDI. 2,4-TDI is prepared in three steps from toluene via dinitrotoluene and 2,4-diaminotoluene

(TDA). Then, the TDA is treated with phosgene to form TDI. HDI is produced by the reaction of hexamethylene diamine with phosgene.

14.1.4 Current Production Trends

The chief factor driving the global isocyanate market is the growing end-use segments for the polyurethane industry. It is estimated that the Asia Pacific region is expected to have significant growth in the future due to growing end-use industries such as construction, electronics, and automotives. North America is expected to have moderate demand whereas Europe is anticipated to grow at a sluggish rate (Grand View Research 2017). According to a recent market analysis and forecast study, the worldwide production of TDI had a steady increase trend in the past several years (Merchant Research and Consulting 2014). The overall TDI production volume exceeded 2.29 million tons in 2011 in which Asia accounted for approximately half of the world TDI production. In 2017, the worldwide TDI production volume is poised to go beyond 2.7 million tons. Total world production of MDI and polymeric MDI (PMDI) is over 5 million tons per year.

14.1.5 Isocyanate Use

Isocyanates-based polyurethane polymers are extensively used in various end-use industries, such as in many daily life consumer products and in the manufacture of flexible and rigid foams, fibers, and elastomers. Isocyanates are used as insulators in electronic industry, as vehicle exteriors to reduce vehicle weight, or in car seats in the automotive industry, as flooring materials, decorations, and building insulation materials in the housing industry, as carpet cushion, mattress padding, or surface polish in the furniture industry, and as components in paints and varnishes for surface coating such as in the auto body repair and refinishing industries (American Chemistry Council 2017). Spray-on polyurethane products containing isocyanates have been developed also for a wide range of other retail, commercial, and industrial uses to protect cement, wood, fiberglass, steel, and aluminum, including protective coatings for truck beds, trailers, boats, foundations, and decks (NIOSH 2014a).

Aliphatic diisocyanates are specialty intermediate chemicals used primarily to make durable coatings, adhesives, sealants, and elastomers, which are used in significantly smaller quantities than the aromatic diisocyanates. In total, aliphatic diisocyanates represented less than 5% of overall isocyanate consumption in the North American polyurethane industry (American Chemistry Council 2017). Aliphatic diisocyanates are sold primarily to industrial customers who use them as binders or hardeners during manufacturing processes to form polyisocyanates that are color-stable, durable, and can significantly enhance a product's appearance, lengthen its lifespan, and offer high abrasion and UV resistance. These aliphatic polyisocyanates are used in paint and surface coatings applied in the automotive, marine, and aircraft industries. Aliphatic diisocyanates are also used to make urethane-based polymers which are formulated into heat-activated or contact adhesives. Typical uses include adhering wood on wood, polyvinyl chloride lamination on wood, automotive, footwear, and construction applications or as construction sealants and in leather refinishing, textile and fiber treatments, ink, thermoplastic polyurethane sheets, and others (American Chemistry Council 2017).

There are two primary aromatic diisocyanates: TDI and MDI. TDI is used primarily in the production of flexible foams. MDI comes in two forms: pure MDI and PMDI. Pure MDI is used in the production of a variety of polyurethane products such as elastomers, sealants, adhesives, and coatings. PMDI is a highly versatile product used to produce a wide variety of rigid, flexible, semi-rigid, and polyisocyanurate and thermoset foams. There are also less common aromatic diisocyanates, such as NDI described earlier and p-phenylene diisocyanate (PPDI).

14.2 Occupational Exposures

14.2.1 Airborne Exposures for Workers

Isocyanates are the raw materials that make up all polyurethane products. Jobs that may involve exposure to isocyanates include painting, foam-blowing, and the manufacture of many polyurethane products. Over the years in an effort to reduce worker exposures to isocyanates, manufacturers have made some products, particularly spray paints and varnishes, to contain more polyisocyanates and less monomers. However, exposure to isocyanates still exists. More recent studies show that exposures are variable among different industries and job categories and are also probably affected by different sampling and analytical methods used. It also seems exposures during spray-painting operations are much higher than in an isocyanate manufacturing setting. A survey of airborne isocyanate exposure in 13 Swedish polyurethane industries by Sennbro et al. (2004) with 223 personal and area air samples from molding, continuous foaming, flame lamination, and low and no heating processes found that total isocyanates were in the range of 0.004–5.2 ppb with short-term stationary monitoring levels of up to 38 ppb in the flame lamination plants. Another study conducted by Pronk et al. (2006) in the Netherlands evaluated personal exposures in spray operations in 23 auto body shops and 5 industrial painting companies. The results showed that exposure was the highest for HDI that varied from non-detectable to 2643 $\mu g/m^3$ NCO (a unit based on the weight or mass of total isocyanate functional groups) whereas TDI exposure was more often found in auto body spray painting than in industrial painting, but the levels were much lower. Exposure to MDI was found incidentally during auto body shop spray painting and welding tasks (non-detectable to 0.5 μg/m^3 NCO). Woskie et al. (2004) in the Survey of Painters and Repairers of Autobodies by Yale (SPRAY) study in Connecticut, USA, collected 380 samples for airborne isocyanates from 33 auto body shops. The median total reactive isocyanate concentrations (aliphatic isocyanates) were: 206 μg NCO/m^3 for spray operations, 0.93 μg NCO/m^3 for samples collected in the vicinity of spray operations done on the shop floor (near spray), 0.05 μg NCO/m^3 for office or other shop areas adjacent to spray areas (workplace background), 0.17 μg NCO/m^3 for paint mixing and gun cleaning operations (mixing), and 0.27 μg NCO/m^3 for sanding operations. Another study conducted in a large foundry with 332 workers in Sweden found an average personal air concentration of 0.55 μg/m^3 for MDI, a 50-fold lower than the Swedish occupational exposure limit of 30 μg/m^3 (Liljelind et al. 2010).

14.2.2 Airborne Occupational Exposure Limits for Various Types of Isocyanates

The above studies represented exposure levels of various types of isocyanates encountered in different countries and industrial settings. To put these exposure levels into perspective, it is necessary to compare them with current occupational exposure limits (OELs). Table 14.1 lists exposure limits from various organizations as summarized by Bello et al. (2004). This indicates that the U.S. Occupational Safety and Health Administration (OSHA) currently does not have permissible exposure limits for aliphatic isocyanates and HDI polyisocyanates. There are no time-weighted average (TWA) exposure limits for aromatic isocyanates, and only a ceiling limit exists. The National Institute for Occupational Safety and Health (NIOSH) and American Conference of Governmental Industrial Hygienists (ACGIH) both have recommended exposure limits/threshold limit values for aliphatic and aromatic isocyanate monomers, but not polyisocyanates. Bayer Corporation has their internal exposure guidelines for polyisocyanates. All of the above OELs are isocyanate-specific and based on the monomer mass in μg/m^3. The United Kingdom-Health and Safety Executive (UK-HSE) and Sweden use the unit based on the mass of all NCO groups in the samples that do not need to distinguish the types of isocyanates. Both OELs had 20 μg/m^3 as the TWA exposure limit, whereas for the short-term exposure limits (STELs) Sweden has 44 and UK-HSE has 70 as the OEL. It is clear that average worker exposure in the SPRAY study in Connecticut (Woskie et al. 2004) and the highest exposure in the Netherlands study (Pronk et al. 2006) for spray operations are well above the Swedish and UK-HSE OELs using the NCO unit. The mass-based unit can be converted to the NCO-based unit which allows the assessment of exposure to total isocyanates regardless of isocyanate types and physical and chemical states (monomer vs. polymer and vapor vs. aerosol). For more details on the conversion method, see Bello et al. (2004).

TABLE 14.1

Current USA (OSHA, NIOSH, and ACGIH), UK-HSE, and Swedish Exposure Limits (μg/m^3 Air) for Isocyanates

		OSHA PEL		NIOSH REL		ACGIH® TLV®		Swedish TLV		Bayer Corp. Guidelines		UK-HSE	
Isocyanate Species		**TWA 8-hr**	**Ceiling**	**TWA 10-hr**	**Ceiling 10-min**	**TWA 8-hr**	**STEL 15-min**	**TWA 8-hr**	**STEL 5-min**	**TWA 8-hr**	**STEL 15-min**	**TWA 8-hr**	**Ceiling 10-min**
Aromatic diisocyanates	TDI	–	140 (68)	CA-LFC[a]	–	36 (17)	140 (68)			–	–		
	MDI	–	200 (67)	50 (17)	200 (67)	51 (17)	–			–	–		
	NDI	–	–	40 (16)	170 (68)	–	–			–	–		
Aliphatic diisocyanates	HDI	–	–	35 (18)	140 (70)	34 (17)	–			–	–		
	IPDI	–	–	45 (17)	180 (68)	45 (17)	–			–	–		
	HMDI	–	–	–	–	54 (17)	–			–	–		
Polyisocyanate	HDI polyiso[b]	–	–	–	–	–	–			500 (110)	1000 (220)		
Universal standard	TRIG[c]	–	–	–	–	–	–	(20)[d]	(44)[d]	–	–	(20)	(70)

Source: Bello D et al. *Am J Ind Med* 2004;46(5):480–91. With permission.

Note: Values in brackets are converted unit in μg NCO/m^3.

[a] NIOSH considers TDI to be a potential occupational carcinogen (CA) and recommends that exposures be reduced to the lowest feasible concentration (LFC).

[b] This standard applies only to HDI-based polyisocyanates biuret and isocyanurate expressed as bulk product, excluding the HDI monomer. The state of Oregon has promulgated the same standards as Bayer's recommended values.

[c] TRIG = Total reactive isocyanate group in μg NCO group/m^3. The standard applies to all isocyanates (monomers, polyisocyanates, and their mixtures) regardless of their origin.

[d] The Swedish standard is based on 5 ppb (TWA), which equals 90 μg HDI-biuret/m^3 (20 μg NCO/m^3), and 5-min STEL of ~13 ppb, which equals 20 μg HDI-biuret/m^3 (44 μg NCO/m^3).

14.2.3 Health Effects of Isocyanate Exposure

The main concern with exposure to isocyanates is respiratory disease, particularly asthma. Isocyanates are powerful irritants to the mucous membranes of the respiratory tract, gastrointestinal system, and eyes that can cause inflammation (NIOSH 2014a). Isocyanates are also potent sensitizers and exposed workers can get sensitized (Redlich et al. 2001). Both animal and human epidemiologic studies have shown that skin exposure can induce initial sensitization (Bello et al. 2007). Respiratory exposure to isocyanates alone can also lead to sensitization. Sensitized workers are subject to severe bronchial asthma attacks if they are exposed again through the respiratory tract even at low levels (NIOSH 2014a). It is well known that diisocyanates are the most commonly identified cause of occupational asthma (OA) in industrialized countries (Chan-Yeung 1995, Redlich et al. 2001). It is also found that TDI, MDI, and HDI in both the monomer and polymer forms all can cause OA and there is a cross reaction to different types of isocyanates in sensitized workers (Innocenti et al. 1988).

There is a dose–response relationship between isocyanate exposure and the risk of asthma; the higher the exposure the greater the risk for OA (Meredith et al. 2000). Ott et al. (2003) reported that in the early years of the industry, annual incidence rates of OA due to TDI was much higher ranging from 1% to as high as 5%–6%. However, since the mid-1970s, annual OA incidence rates have been <1%, where 8-h TDI concentrations have been maintained below 5 ppb. They indicated that there is evidence that the majority of OA cases may be attributable to TDI concentrations well above 20 ppb associated with overexposure incidents.

Although isocyanates are identified as the most common cause of OA, the mechanism is still not very clear. It is believed that isocyanate asthma is non-IgE related because specific IgE antibodies have been identified in only a very small proportion of patients proven to have the disease by inhalation challenge tests (Chan-Yeung 1995). Isocyanates can interact with albumin and other proteins in the skin (such as keratin) and respiratory tract (epithelial cell protein) to form antigenic conjugates which further induce other immunologic responses (such as production of isocyanate-related immunoglobulins or stimulation of lymphocyte proliferation (Wisnewski et al. 1999, 2000). While the detection of isocyanate IgE protein conjugate indicates a health effect outcome, a detection of IgG protein conjugate more represents an exposure to isocyanates (Chan-Yeung 1995).

Isocyanate exposure may also cause hypersensitivity pneumonitis. Sporadic cases have been reported in an auto body shop of HDI exposure (Seldén et al. 1989), and exposure to TDI (Charles et al. 1976, Fink and Schlueter 1978, Nielsen et al. 1985), and MDI (Paisley 1969, Tanser et al. 1973, Malo and Zeiss 1982) in various work settings have also been reported. NIOSH also considers TDI as a potential occupational carcinogen. In the Current Intelligence Bulletin 53, NIOSH reviewed scientific evidence and concluded that recent animal studies have demonstrated that commercial-grade TDI and 2,4-TDA are carcinogenic in rats and mice. However, there is no epidemiologic evidence that any isomer of TDI or TDA has induced cancer in exposed workers (NIOSH 2014b).

14.3 Controlling Isocyanate Exposure in the Workplace

14.3.1 Negative Pressure Air-Purifying Respirators versus Supplied-Air Respirator (SAR)

Isocyanate asthma persists despite negligible ongoing TDI exposures or even after removal from the workplace (Pisati et al. 1993, Vandenplas et al. 1993). Over time, sensitized workers with asthma will have an accelerated rate of decline in lung function. Therefore, prevention by controlling or reducing exposure to isocyanates is very important (Fink and Schlueter 1978).

For general industry, OSHA addresses isocyanates in 29 CFR 1910 Subparts H and Z where the general hierarchy of exposure control methods applies to air contaminants. OSHA indicated that "administrative or engineering controls must first be determined and implemented whenever feasible. When such controls are not feasible to achieve full compliance, protective equipment or any other protective measures shall be used to keep the exposure of employees to air contaminants within the limits. Any equipment and/or technical measures used for this purpose must be approved for each particular use by a competent industrial hygienist or other technically qualified person. Whenever respirators are used, their use shall comply with 1910.134," the OSHA's respiratory protection program (OSHA 2016).

More specifically, when responding to a request by the 3M Occupational Health and Environmental Safety Division, OSHA clarified its position on the selection of air-purifying respirators (APRs) for gases and vapors with poor warning properties, such as common diisocyanates. In its July 18, 2000 letter, OSHA stated that "the employer shall select and provide an appropriate respirator based on the respiratory hazard(s) to which the worker is exposed and the workplace and user factors that affect respirator performance and reliability." OSHA indicated that, "For atmospheres which are not immediately dangerous to life or health (IDLH), APRs are now considered acceptable as long as appropriate precautions and change out schedules are in place, even for use against substances with poor warning properties." OSHA allows the employers to evaluate their workplace exposure and select appropriate respirators for their employees to use against exposure to isocyanates such as APRs or powered air-purifying respirators (PAPRs) and does not require the use of supplied-air respirators (SARs) anymore (OSHA 2000). However, OSHA maintains that any respirator selected must be used in the context of a written respiratory program that includes various components such as medical assessment, respirator use training, initial fit testing, and further testing on an annual basis, cartridge and filter change schedule, and maintenance (cleaning, disinfection, and storage) of respirators.

In addressing the exposure control for TDI and TDA, NIOSH recommended that, "equipment maintenance and worker education are vital aspects of a good occupational health and safety program. Workers must be informed of (1) any materials that may contain or be contaminated with TDI or TDA and (2) the nature of the potential hazard [29 CFR 1910.1200]. Employers must transmit this information by means of a hazard communication program, which is to include container labeling, material safety data sheets (MSDSs), and worker training. Every attempt should also be made to minimize exposure to TDI and TDA by using work practices and controls such as product substitution, closed systems and ventilation, worker isolation, protective clothing and equipment, respiratory protection, decontamination and waste disposal, and medical monitoring" (NIOSH 2014b).

As to the use of respiratory protection against TDI/TDA, NIOSH maintains that, "only the most protective respirators should be used for situations involving carcinogens. These respirators include any self-contained breathing apparatus with a full facepiece operated in a pressure-demand or other positive-pressure mode, and any supplied-air respirator with a full facepiece operated in a pressure-demand or other positive-pressure mode in combination with an auxiliary self-contained breathing apparatus operated in a pressure-demand or other positive-pressure mode" (NIOSH 2014b).

14.3.2 Efficiency and Effectiveness of APRs against Isocyanates

Since isocyanates can be in the air in either a vapor phase (monomer) or aerosol phase (polyisocyanates) or/and both, an APR either in a negative pressure or a positive-pressure-demand mode and in either half-face or full-face would need both the cartridges and particle filters to remove both. Laboratory testing may control the generation of either a vapor or an aerosol or both to test the efficiency of the cartridge or filter or in combination. However, such laboratory studies on filtration efficiencies are very limited. Dharmarajan et al. (1986) conducted a chamber study in which they evaluated two brands of air-purifying organic vapor cartridges from Wilson and Survivair and a disposable respirator from 3M on the protectiveness against TDI vapor. They found that there was no significant breakthrough (less than 0.5%) of TDI in any of the respirators tested for 40 hrs at 0.2 ppm and for 20 hrs at 1.5 ppm or higher. Vasta (1985) conducted a simulated spray-painting study in a ventilation hood and evaluated the filtration effectiveness of Wilson Products R21 organic vapor cartridge with R15 prefilter and Mine Safety Appliances organic vapor cartridge and prefilter against Imron® for 4 hrs versus 10 hrs and Centari® enamel paints for 15 versus 18 hrs. While there was some solvent breakthrough, no isocyanate breakthrough through the cartridges was detected. Although laboratory testing can better control the generation of the exposure atmosphere, the efficiency may not represent the true protectiveness of the respirators used in the field. Workplace protection factors (WPFs) measured in the actual work environments and tasks can provide better evaluation on the effectiveness against isocyanate exposure.

14.4 Case Study: Auto Body Repair and Refinishing Industry

14.4.1 Auto Body Repair and Refinishing Industry Background

The auto body repair and refinishing industry, or the collision industry, is one of the typical workplaces that represent small businesses where aliphatic isocyanates, mostly HDI and IPDI, are commonly used. The auto body repair and refinishing industry is classified by the North American Industry Classification System (NAICS) as the automotive repair and maintenance category and coded as 8111. The industry is composed of family owned and geographically dispersed auto body shops that have nonuniform work structures and practices (Redlich et al. 2001). They often lack resources for adequate engineering controls and complete respiratory protection programs (Cooper et al. 1993; Heitbrink et al. 1993; Whittaker et al. 2005). In the United States based on the most recent survey in 2016, there are about 40,962 auto body repair and refinishing facilities that are scattered throughout population centers, employing an estimated 187,800 workers (Whittaker et al. 2005). The percentage of small shops (with annual sales under $300,000) has declined significantly since 1995, while the share of large shops (over $1 million) has been increasing significantly (Collision Repair Foundation 2017). Traditionally, these family businesses continued from one generation to another with the owner doing both office work and repair or spray painting or employing from a few workers to over 20 workers. The average number of workers was around seven (Sparer et al. 2004). According to the owners, the young generation tends to go to college with better paid jobs and does not often wish to continue their family businesses. The average technician age has increased to almost 41 years old, rising about 13% since 1995. A particular concern for this industry is the growth in the percentage of technicians over 50 years old and lack of qualified young workers to continue the business, although there are some auto body shop technician schools providing auto body repair and refinishing training (Collision Repair Foundation 2017).

14.4.2 Auto Body Shop Work

Generally, office workers work in the front office estimating the prices for damage repair and doing bookkeeping. Body repair technicians repair the body damage, but they can also do some primer coating or sealer coating mostly on the shop floor that creates some opportunities of exposure for workers nearby (bystander exposure) whereas spray painters mostly paint the surfaces of repaired cars mostly in a spray booth.

Damaged cars are repaired with different approaches and methods depending on the degree of damage. Each car is different in its repair. Damaged parts will be repaired, such as wiring and ventilation system repair. Crumpled parts are replaced with new parts if no longer reusable. New parts are often lightly sanded and painted with sealer coating (sealing). Areas with dents are repaired with the dents mechanically pulled up, hammered flat, or filled in with two-part plastic materials. This process is called bondo (Sparer et al. 2004). Filled-in plastic materials are quickly hardened, and sanding with finer and finer sanding papers is used to make the surface smooth. Areas not to be painted will be covered with paper and taped in place. The area to be painted is then painted with the primer or undercoat and then with the base coat or color coat. The final coat is the clear coat. Each type of coating requires several coats ranging from one to three or four coats. Spray-painting work involves paint mixing where isocyanate-containing hardeners are mixed with the paint (sealer, primer, color paint, or clear coat) and reducer (containing several types of organic solvents) in certain proportions, deepening on the type of coating and type of paint manufacturers' requirements, such as 3:1:1 (3 parts of paint, 1 part of hardener, and 1 part of reducer), spray painting inside a booth and gun cleaning. Painted cars will be baked with high temperature for about 30 minutes to speed up polyurethane curing. After curing, technicians will un-tape the car. Buffing and compounding to make the surface smoother or polishing maybe performed. Then detailing work will be done to wash the exterior and make it ready for pickup (Sparer et al. 2004).

14.4.3 Auto Body Shop Work Hazards

Workers in this industry are exposed to a variety of respiratory hazards, including silica from sandblasting operations and dust from sanding and bondo work; metal fumes from cutting, grinding, and welding during body frame repair; hexavalent chromium from spray-painting operations; volatile organic compounds from paint mixing, priming, sealing, base coating and clear coating, gun cleaning and bondo work (styrene); and isocyanate vapor and aerosols from spray painting. Physical hazards include repetitive stress and other ergonomic injuries, noise, lifts, cutting tools, and oil and grease on walking surfaces. Due to the concern with the risk of asthma, exposure to isocyanates is of a main concern among other health hazards.

Many factors in auto body shops can affect the exposure of workers. Isocyanates used in auto body shops are contained in hardener products which largely have oligomers (polymer form of HDI or IPDI) as the main form with 1% or less monomer content. The spray-painting operation uses high-volume low pressure (HVLP) air spray guns that nebulize the mixed paints into both vapor and aerosol forms. This requires a respirator with both paint prefilters to remove isocyanate aerosol and paint solids and dual cartridges for removing isocyanate vapor and other organic solvents. Exposure to isocyanates in spray operations are typically much higher in the auto body work industry than in other industries due to the large quantities of paints released in the air in a short period of time. Engineering control with a fabricated spray booth significantly reduces exposure to isocyanates when compared to spraying/priming on the shop floor where bystanders may not be wearing a respirator. However, the type of ventilation of the booth such as downdraft versus semi-down or side draft as well as the scheduled change of the booth filters affect the efficiency of isocyanate removal. Some shops use a prep station for painting where there is an open front door with some plastic strips as a curtain. Even further, some shops do not have a fabricated booth installed and only have a so-called homemade booth where a large building room serves as both with a fan on the wall. The efficiencies of these ventilation systems are less optimal and may increase exposures. This requires that respirators be used as the last line of defense.

14.4.4 Auto Body Shop Regulation

Many OSHA standards apply to the auto body repair and refinishing shops, such as 1910 Subpart H, hazardous materials 1910.107, spray finishing using flammable and combustible materials, 1910 Subpart I, personal protective equipment, 1910.134, respiratory protection, 1910 Subpart Z, toxic and hazardous substances, and 1910.1200, hazard communication. Out of the total 1547 OSHA citations during the period October 2015 through September 2016, the most cited causes were hazard communication standard and respiratory protection standard (OSHA 2017). Additionally, regional OSHA offices have a local emphasis program, including inspections and a required respiratory protection program to reduce workplace health hazards associated with auto body shop work.

14.4.5 Auto Body Shop Performance in Respiratory Protection Programs

In the early 1990s, NIOSH researchers visited a few auto body shops and evaluated their respiratory protection programs along with other health and safety issues. They typically found no respiratory program in place (Cooper et al. 1993; Heitbrink et al. 1993).

To answer this question better, from 1997 to 2002 (Woskie et al. 2004; Liu et al. 2006) SPRAY study researchers conducted a survey in 36 auto body shops in Connecticut, USA to evaluate their respiratory protection programs. Questions and field observations focused on whether a written program was established in the shop, if employees were trained to use respirators, if

TABLE 14.2

Respiratory Program and Respirator Types used in Connecticut, USA

	Number of Shops	(%)
Painting and priming respirator		
3M OV/P95[a] reusable	10	(28)
3M OV/P95 disposable	28	(78)
SAS[b] OV/N95[c] reusable	24	(67)
SAS OV/N95 disposable	3	(8)
Other brands[d]	23	(64)
Supplied-air respirator usage for painting and priming		
3M	14	(39)
SAS	2	(6)
Other	7	(19)
Non-painting-task respirator		
3M reusable OV/P100[e]	3	(8)
3M disposable OV/P100	1	(3)
SAS reusable OV/P100	1	(3)
3M N95 dust mask	11	(30)
Written respirator protection program	11	(30)
Employees trained to use respirator	19	(53)
Fit testing ever conducted	15	(42)

Source: Liu Y et al. *J Occup Environ Hyg* 2006;3(5):234–49.

[a] OV/P95: Organic vapor cartridges and P95 oil-proof particle prefilter.

[b] SAS: Survivair System.

[c] OV/N95: Organic vapor cartridges and N95 nonresistant to oil particle prefilter.

[d] Other brands: Including MSA, Binks, etc. (refer to text for more details).

[e] OV/P100: Organic vapor cartridges and oil-proof, high-efficiency particulate air prefilter.

medical screening was provided for respirator users, and if any fit testing had been previously conducted. Information on the type, brand, coverage, and cartridges of various respirators provided in the shop for spray painting, priming, and body repairs was also collected. Table 14.2 summarizes the results and shows that 3M and SAS were the dominant respirator brands. Other respirator types used included MSA, Wilson, North, Binks, AO Safety, Gerson, and Sata. Out of 36 shops, 23 shops (64%) provided a SAR for painting (20 shops, 56%) and priming (3 shops, 8%). 3M was the major supplier of SAR (14 shops, 39%). Actual use of SAR, however, was observed only in 11 (30%) shops during the survey time (Liu et al. 2006). The most commonly stated reason that painters did not use SARs was that the airline hoses were cumbersome. A written respiratory protection program was reported in 11 shops (30%), 19 shops (53%) had their employees trained to use respirators, and 15 shops (42%) had previously conducted fit testing for their employees. No medical screening or respirator maintenance program was provided in any of these shops. In comparison with earlier surveys conducted by NIOSH that showed no written respiratory protection programs in the shops, the SPRAY results indicated some improvements in respiratory protection in the Connecticut shops.

In a more recent and comprehensive survey study of spray-painting operations in the state of Washington, USA, Whitaker et al. (2005) found that SARs with a supply hose were used in 58% of shops (26% for full-face, 18% for hooded or head-covered, and 14% for half-face) and that was much higher than in the SPRAY survey (Liu et al. 2006). APRs were used in 85% of shops (46% for half-face, 23% for disposable half-face, and 16% for full-face). Hooded PAPRs were used in 8% of the shops and dust masks in 3% of the shops. Similarly, the primary reason workers cited for not using SARs was that workers did not like them. As this study boasted a 69% response rate, it provides a reasonable picture of respirator usage in the industry.

14.4.6 APR Protection in Auto Body Shops

WPF based on workplace sampling is a better indicator of respirator protectiveness, but such studies are limited in number as they are expensive to conduct and personal air samples both outside the mask and inside the mask need to be collected. WPF studies in auto body shops for the use of APRs against isocyanates are even scarcer. Rosenberg and Tuomi (1984) in Finland measured airborne concentrations of HDI-based oligomers in three car paint shops and in one trade school for car painters during spray-painting operations. They also evaluated a few pairs of outside versus inside-mask concentrations. The WPF calculations for APRs ranged from 4.1 to 96 for monomers and from 5.6 to 780 for oligomers.

The SPRAY study researchers collected 29 pairs of outside/inside APRs with dual cartridges and paint prefilters. WPFs ranged from 1 to 204 with a geometric mean (GM) of 17 (geometric standard deviation [GSD] 4) for HDI, from 7 to 9777 with a GM(GSD) of 388(4) for pHDI, from 20 to 1489 with GM(GSD) of 358(3) for pIPDI, and from 9 to 5335 with GM(GSD) of 319(4) for total NCOs. The fifth percentile protection factor was 54 for total NCOs, which is above the OSHA assigned protection factor 10 for these respirators (OSHA 2009).

To help auto body shops formulate a control strategy matrix that guides the selection of specific respiratory protection to be used with particular spray-painting booths, a voluntary program called Product Stewardship Partnership was initiated by members of paint manufacturers, EPA, OSHA, NIOSH, and automotive repair associations. The paint manufacturers' stewardship program recommended that respirators with APF ≥ 25, such as SARs, be used for side draft booths and APRs with APF ≥ 10 used for downdraft booths (Heitbrink 1998). The SPRAY study found the fifth percentile of WPF to be 72 for downdraft booths (N = 18) and 54 for cross draft or homemade booths (N = 9), which suggests that negative pressure half-facepiece APRs can provide respiratory protection that meets the minimal APF requirements for booth types (Liu et al. 2006).

14.4.7 Respiratory Protection Training for Auto Body Shops

The SPRAY study also evaluated if training would improve the respirator fit testing results. All workers who used a dual cartridge APR were first quantitatively fit tested without training. If a worker failed the test on first try, training was provided on the proper use of respiratory protective devices and how to do user checks. The worker was instructed to retighten the respirator or select a different size respirator. The quantitative fit test was then repeated. The results showed that out of 142 workers tested, 113 (80%) passed the test on the first try. Reasons for failing included inappropriate donning and loose fitting facepiece, thick beard and facial hair at the facepiece sealing edge, and wrong respirator size. Of those who failed on the first try and were retested after training, redonning, and tightening of the respirator, or offered another respirator size, 78% passed the second test. Overall, 92% of workers passed after the first and second tests. The pass rate on first try was significantly higher ($p = 0.04$) for workers who reported to have been fit tested on a previous occasion (92%, N = 53) versus those without previous testing (72%, N = 86). This indicates that proper training on respirator use and selection of a correct respirator size can significantly improve both fit test pass rate and fit factors, highlighting the importance of establishing a full workplace respiratory protection program (Liu et al. 2006).

14.4.8 Correlation between Fit Test Score and WPF for Isocyanates

In general, earlier studies found little or no correlations between fit factor and WPF measured in the workplace using the assumption of simple linearity (Zhuang et al. 2003; Lee et al. 2004; Nicas and Neuhaus 2004). To explore this relationship further, the correlation between the fit factor data for those workers who were also measured for WPF was analyzed in the SPRAY study (Liu et al. 2006). It was found that there was a positive increase in WPF when the fit factor increases to a certain point (450) where further increase in the fit factor would result a decrease in WPF. One explanation for this observation is that to achieve a very high fit factor, the respirator must be worn very tightly and the worker cannot tolerate that tightness in the hot spray-painting environment so he loosens it during the WPF testing, producing the downward slant of the WPF to the fit factor relationship. In the field, SPRAY researchers tended to observe that spray painters took off the respirator inside the booth in between coats to inspect the paint quality. This habit possibly is due to the respirator being too tight to be tolerated for long.

14.5 Conclusions

This chapter summarizes respiratory protection against exposures to isocyanates using the auto body repair and refinishing industry as a special case. Isocyanates are potent sensitizers and can cause asthma and pneumonitis in exposed workers. While the general hierarchy of exposure controls should be used, not all control measures can be applied to or be feasible for all shops. Strategies have to be tailored to each shop based on their situation. Recent product developments have made it possible to substitute regular paints with non-hardener (non-isocyanate) paints, but hardeners are still needed for the clear coats. Ventilation using fabricated booths may not be affordable to all shops and even so, downdraft booths may not remove all the isocyanate vapor and aerosol. Administrative control is important for the shop owners not only to provide needed programs to comply with OSHA standards, but also to train workers on the proper use of hazardous isocyanates and other chemicals, and select and use appropriate respirators. Respiratory protection, although a last line of defense, needs to be used for all workers especially for those who perform paint mixing, priming, sealer coating, base coating, clear coating, and gun cleaning tasks. Use should be under the auspices of a complete written respiratory program that includes medical evaluation, proper training, fit testing, cartridge and filter change schedule, and regular maintenance in respirator cleaning and storage. While SARs and PAPRs provide higher protection and more comfort, the laboratory and field WPF testing demonstrated that negative pressure, half- or full-face APRs with dual cartridges and paint prefilters can be used for protection against isocyanates. It is important to note that since skin exposure to isocyanates can cause respiratory sensitization, protective clothing use in the form of gloves and coveralls are also very important, especially for spray painters. Future intervention studies to identify other exposure control measures versus respiratory protection need to be conducted.

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15

Application of Activated Carbon Fibers in Respiratory Protection for Volatile Organic Compounds

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15.1 Introduction

Approximately 5 million workers in 1.3 million workplaces in the United States are required to use respirators for protection against airborne pollutants that may cause diseases or death (OSHA, n.d.a). A significant number of deaths and illnesses, such as cancer and lung impairment, may be prevented annually through proper use of respirators. However, workers have poor compliance in respirator use because of various difficulties and issues, including discomfort experienced by the wearer. Thus, there is a need to develop better respirators to address such discomfort-related and other issues, thereby increasing user compliance and improving worker protection against airborne contaminants. Several researchers have investigated various adsorbent materials that may be used to create improved respirators against gaseous air pollutants; these materials include activated carbon fibers (ACFs). This chapter discusses several conducted studies that investigated the properties of ACFs and their potential application for respiratory protection against volatile organic compounds (VOCs) based on breakthrough, adsorption capacity, critical bed depth, and pressure drop.

15.2 Background

15.2.1 Granular Activated Carbon

Granular activated carbon (GAC) is currently the standard adsorbent used in respiratory protection against VOCs and other gas-phase contaminants because of its efficiency, low cost, and available technology. However, GAC has certain drawbacks including the need for containment, attrition of the granular material, and particle entrainment (Feng et al., 2005). Because of its granular nature, GAC needs to be contained in a cartridge or canister, which contributes to the weight and bulkiness of the respirator in addition to the weight of the GAC itself. This tends to make respirators less comfortable to wear, which can result in poorer user compliance. Many studies have shown that respirator use is associated with overall discomfort (Terrell, 1984; Eck and Vannier, 1997; Salazar et al., 2001; Goldfrank and Liverman, 2007; Radonovich et al., 2009; Baig et al., 2010). Workers who did not use or who have less intent of using respirators believe that wearing a respirator is uncomfortable (Salazar et al., 2001; Baig et al., 2010). A series of surveys of safety professionals revealed a high rate of noncompliance in wearing personal protective equipment (PPE) when necessary, with discomfort as the main cause (Matela, 2009). Moreover, lightweight respirators are significantly rated as more comfortable than heavy ones (Hooper et al., 2001) and, thus, are more likely to be worn. Thus, the development of improved respirators that are lighter, thinner, and more efficient in protecting against airborne pollutants may improve worker compliance on respirator use.

15.2.2 Activated Carbon Fiber

ACFs have been considered as an alternative adsorbent to GAC since it has been shown to be effective in capturing VOCs from gas streams at a wide range of concentrations (Tanada et al., 2000; Ramirez et al., 2004; Sullivan et al., 2004; Fournel et al., 2005; Mallouk et al., 2010). ACFs are obtained from the carbonization and activation of polymeric fibers from various precursors, such as viscose rayon, phenolic resin, polyacrylonitrile, and pitch (Suzuki, 1994). The small fiber diameter of ACF (ranging from 10 to 20 μm) allows homogeneous activation of the fibers, resulting in a unimodal, narrow pore size distribution in the micropore range (Lu and Zheng, 2002; Feng et al., 2005).

15.2.3 Pore Structure of ACF

The pore structure of activated carbon is very important in terms of adsorption of airborne contaminants. Pores are classified according to pore width by the International Union of Pure and Applied Chemistry (IUPAC) into micropores (<2 nm), mesopores (2–50 nm), and macropores (>50 nm) (Gregg and Sing, 1982). One of the unique features of the ACF compared to traditional active carbon forms is its microporosity. Unlike the GAC with a more complex porous network (i.e., macropores branching to mesopores then to micropores), ACF has micropores that are directly accessed from the fiber surface by adsorbates, resulting in faster adsorption/desorption kinetics (Suzuki, 1994; Lu and Zheng, 2001; Huang et al., 2002; Zhang et al., 2011). Micropores in all activated carbon forms are important because most of the adsorption takes place in the micropores. Interaction potential in micropores is significantly greater than in wider pores due to the proximity of the pore walls, resulting in the overlap of the potential fields from neighboring pore walls and the corresponding enhancement of interaction energy of the adsorbent with the gas molecule (Gregg and Sing, 1982). Micropores are preferentially filled at lower concentrations due to this overlapping of attractive forces of opposite pore walls, and are primarily responsible for adsorption at low VOC concentrations in ambient air environments (Gregg and Sing, 1982; Foster et al., 1992; Derbyshire et al., 2001). Thus, given its microporous structure, ACF is expected to have an excellent adsorption of airborne pollutants at low ambient concentrations.

15.2.4 Advantages of ACF

ACFs have several advantages over traditional activated carbon adsorbents such as GAC, including their larger surface area, higher adsorption capacities and rates, thinner critical bed depth, greater number of micropores, and faster thermal and mass transfer properties (Petkovska et al., 1991; Tsai et al., 2008; Balanay et al., 2011; Balanay and Lungu, 2012). Kudryavtseva et al. (1998) recognized the potential of ACFs in the development of comfortable, light-duty gas respirators and investigated the optimum properties of ACF for such application. A comparison of the toluene adsorption between GAC and ACF types showed that ACFs with BET (Brunauer, Emmett, and Teller) surface areas of 1500 m^2/g to have higher adsorption capacities than GAC with a higher BET surface area of 1800 m^2/g (Balanay et al., 2011). ACF is also easier to handle than GAC since it can be manufactured in various fabric forms, such as cloth and felt (Suzuki, 1994; Lu and Zheng, 2001; Huang et al., 2002).

15.2.5 ACF Applications

Several studies have been conducted to assess ACF in air pollution control devices, usually in the form of fixed bed reactors (Takeuchi et al., 1993; Huang et al., 2003; Cheng et al., 2004; Das et al., 2004; Hashisho and Rood, 2005; Lorimier et al., 2005). In such applications, ACFs have been shown to be very effective adsorbents to capture and/or recover water vapor and organic vapors, such as methyl ethyl ketone (MEK), benzene, toluene, xylene, cyclohexanone, tetrachloroethylene, acetone, isopropanol, ethyl acetate, isobutane, and dichloromethane, from gas streams at a wide range of concentrations (Ramirez et al., 2004; Sullivan et al., 2004; Fournel et al., 2005; Mallouk et al., 2010). Filters composed of a mat of ACFs have also been applied in the capture of toxic gases emanating from industrial processes and gasoline vapors from automobile tanks (Kohata et al., 1980). These filters have been extensively used for capture of other gaseous compounds, such as Freon (Fukuda et al., 1989; Zhang et al., 2011). The applications of ACF include environmental cleaning, recovery of sulfur dioxide and nitric oxide in flue gas, energy saving and storage such as methane storage, carbon dioxide (CO_2) capture, and air separation (Kisamori et al., 1994; Mochida et al., 1994; de la Casa-Lillo et al., 2002; Lozano-Castello et al., 2002; Shen et al., 2011; Liu and Adanur, 2014; Su et al., 2014). However, studies on the application of ACF for respiratory protection in the literature are limited.

15.2.6 Significance of the ACF Study

The assessment of the characteristics of ACFs is very crucial in determining if these materials may be used for respiratory protection. Given their advantages, ACFs are a promising alternative adsorbent for the development of thinner, lighter, and efficient respirators. Light N95-like respirators made of ACFs that are compact, easier to wear, and potentially regenerable (e.g., through thermal treatment) may be developed in the future. Such device of reduced size, weight, complexity, and cost may be extremely useful as an escape mask as short-term protection for workers or the public, in case of accidental or intentional release of toxic gases and vapors in a catastrophic event, as well as during routine work (Balanay et al., 2011). Understanding the adsorption and other important characteristics of different types of ACF may potentially lead to the development of more efficient and acceptable respirators for gases and vapors, as well as potentially expand to other PPE uses.

15.2.7 Purpose of the ACF Study

Our ACF research studies were conducted in two phases. Study Phase 1 involved the determination of three adsorption characteristics, which are breakthrough, adsorption capacity, and critical bed depth, of commercially available ACFs for toluene. Study Phase 2 involved the determination of pressure drop of commercially available ACFs in realistic respirator cartridges. In this chapter, the methodology and results of our ACF research are described and discussed by study phase.

15.3 Study Phase 1: Determination of Adsorption Characteristics

To provide adequate protection against high concentration exposures or longer term low-level exposures at or near the occupational exposure limit (OEL), adsorption characteristics of different types of commercially available ACFs must be understood across a wide range of concentrations for specific chemicals to determine potential levels of protection afforded when used in respiratory protection. These adsorption characteristics will determine in advance how thin an ACF respirator can be made and obtain the service life estimates of the ACF respirator. The purpose of this study phase was to determine and compare the breakthrough, critical bed depths, and adsorption capacities of different types of commercially available ACFs for toluene. The main goal of such a comparison is to determine the type of ACF that is most suitable for respirator application.

15.3.1 Methodology

15.3.1.1 Materials

Two forms of ACF, which are the woven cloth and unwoven felt, were used as adsorbents. The thickness of the ACF cloth (AC) was 0.0625 cm and the ACF felt (AF) ranged from 0.2 to 0.3 cm, which was 3–5 times greater than that of the AC. For each form, three different manufacturer-specified surface areas (1000 and 1500 m^2/g for both AC and AF, 1800 m^2/g AF, and 2000 m^2/g AC) were tested. Thus, a total of six types of ACF were analyzed in Phase 1 of the ACF study. Table 15.1 shows the denotation of each ACF based on its nominal surface area and form.

AC10, AC15, AF15, and AC20 were manufactured from novoloid, a phenol aldehyde-based fiber, by American Kynol, Inc. (Pleasantville, NY), while AF10 and AF18 were from viscose rayon fibers by Beijing Evergrow Resources Co. (Beijing, China). The ACFs were cut into 4-cm discs and thermally treated in an oven (Thermo Electron Corporation, Waltham, MA) at 200°C overnight prior to testing to remove moisture and volatile impurities from the ACF materials.

The adsorbate used to challenge the ACFs was toluene (laboratory grade) as the representative VOC since it is one of the most common VOCs in the workplace and is one of the major and most often reported indoor organic vapors (Girman et al., 1999; Larroque et al., 2006). Several studies that tested ACF materials have considered toluene as a representative for the VOC group (Brasquet and Le Cloirec, 1997; Cheng et al., 2004; Das et al., 2004; Tongbao et al., 2004; Fournel et al., 2005; Lorimier et al., 2005). Its adverse effects on humans, due to exposure to concentrations from 200 to 1100 ppm, range

TABLE 15.1

Denotation of ACF Types by Form and Surface Area

	Nominal[a] Surface Area (m^2/g)			
Form	**1000**	**1500**	**1800**	**2000**
Cloth	AC10	AC15	—	AC20
Felt	AF10	AF15	AF18	—

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[a] Manufacturer-specified.

from eye, skin, and mucous membrane irritation, to drowsiness, nausea, and memory loss, to damaged liver and kidney, unconsciousness or even death (ATSDR, 2015). As its exposure limits, toluene has OSHA PEL-TWA of 200 ppm, PEL-C of 300 ppm, PEL-Peak of 500 ppm, and ACGIH TLV of 20 ppm (OSHA, n.d.b). Toluene has lower adsorption capacity onto activated carbons compared to several VOCs, such as benzene, xylene, trichloroethylene, and tetrachloroethane (Hung and Lin, 2007; Li et al., 2012; Ramos et al., 2010). Toluene was purchased from Fisher Scientific (Waltham, MA) and used in the experiments without further purification.

15.3.1.2 Characterization of ACF Structural Properties

The specific surface area and pore characteristics of the ACF samples were measured by nitrogen adsorption at 77 K in the range of relative pressure (P/P_0) from 0.02 to 1 using a Micromeritics ASAP 2020 automatic physisorption analyzer (Micromeritics Corp., Norcross, GA). High purity nitrogen (99.99%) (Airgas, Inc., Radnor, PA) was used in the measurements. Three analyses ($n = 3$) were performed for each ACF type, with a total of 18 physisorption analyses. The actual BET surface area was specifically measured to verify the surface area specified by the ACF manufacturer (nominal surface area).

The pore size distribution of each ACF material was obtained to determine the percentages of micropores, mesopores, and macropores in the adsorbent. The ACF materials were sent to the Instituto de Física Aplicada, Consejo Nacional de Investigaciones Científicas y Técnicas—Universidad Nacional de San Luis (Institute of Applied Physics, National Council of Scientific and Technical Research—National University of San Luis) in Argentina for pore size distribution analyses. The density functional theory (DFT) method was used to calculate the micropore size distribution of the samples, based on a molecular model of adsorption of nitrogen in porous solids (Ryu et al., 2000).

Scanning electron microscopy (SEM) images of the different ACF samples were obtained to visualize the organization, structure, and texture of the fibers. SEM images at 203× magnification were obtained from the Department of Material Science and Engineering, School of Engineering, University of Alabama at Birmingham.

15.3.1.3 Breakthrough Determination

Breakthrough is defined as the permeation of a challenge chemical through the adsorbent. Breakthrough determination was done by challenging the ACF sample with a certain concentration of toluene and detecting the occurrence of breakthrough of toluene by monitoring the effluent downstream of the adsorbent. The materials were challenged with toluene in a stainless steel sample chamber at a constant airflow (16 LPM), temperature (23 ± 0.5°C), and relative humidity (50 ± 10%) and at five different bed depths and mass for a certain concentration. The sample chamber has an internal diameter of 4 cm and was immersed in water for temperature control at 23°C. The mass of the adsorbents was determined before the chemical challenge by using a Denver Model APX-100 analytical balance (Denver Instrument, Denver, CO). The adsorbent bed depths were measured using a caliper. Breakthrough curves were obtained for each ACF type at six different toluene concentrations: 50, 100, 200, 300, 400, and 500 ppm. Duplicates were conducted for 20% of the breakthrough runs. Breakthrough occurred when the effluent concentration exceeded a preset value, such as 10% and 50% of the challenge concentration. The 10% and 50% breakthrough times (i.e., time, in minutes, at which the toluene concentration in the effluent rose to $C/C_0 = 0.1$ and 0.5, respectively, wherein C = effluent or exit concentration and C_0 = inlet or initial challenge concentration) were used to calculate the critical bed depth and the adsorption capacity, respectively, which were both compared across the tested ACFs.

The challenge concentrations chosen for toluene were realistic ambient concentrations found in workplace settings. The air temperature and relative humidity were set at 23°C and 50%, respectively, as these were the standard experimental conditions in laboratory settings used in previous studies on ACF testing, as well as by the National Institute of Occupational Safety and Health (NIOSH) in testing respirators for organic vapors (Cheng et al., 2004; Lorimier et al., 2005; NIOSH, 2006). The airflow of 16 LPM was determined by considering the constant airflow used by NIOSH for the testing of service life of respirators for chemical cartridges (32–64 LPM), possible respirator cartridge diameters (6.9 and 7.2 cm), and the sample chamber diameter of 4 cm.

Toluene vapor was generated by continuous injection of a pre-calculated constant flow of liquid toluene using an Aladdin-1000 automated syringe pump (World Precision Instruments, Sarasota, FL) into a preconditioned stream of air of constant flow. The air was dried by passing through an air drying machine (Hankison, Canonsburg, PA) and a Drierite gas drying unit (W.A. Hammond Drierite Co. Ltd., Xenia, OH). The temperature, relative humidity, and flow of the air were controlled prior to mixing with toluene using a Miller-Nelson Model HCS-401 instrument (Assay Technology, Inc., Livermore, CA). Breakthrough of toluene for each ACF sample was determined by semi-continuous monitoring of the effluent gas using an Agilent Model 6850 gas chromatograph (Agilent Technologies, Alpharette, GA) equipped with a gas sampling loop and flame ionization detector (FID) for quantification. The analytical column used was an HP-1 (100% methyl siloxane) capillary column, 30.0 m×0.32 mm (I.D.)×0.25 μm. The oven temperature was 115°C for 2 minutes. The FID temperature was 230°C. The carrier gas was helium. A 5-point calibration curve was established using the syringe pump to generate five known concentrations. The GC sampling valve was used to sample the known concentration several times at each calibration point in the same manner as breakthrough experiments. Figure 15.1 shows the schematic diagram of the experimental setup for breakthrough determination.

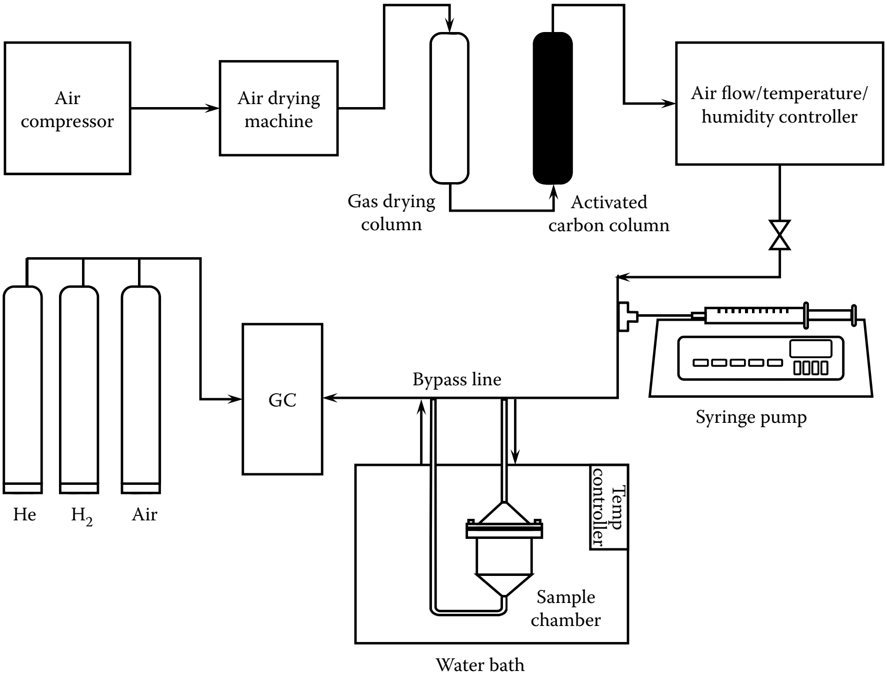
Air compressor
Air drying machine
Gas drying column
Activated carbon column
Air flow/temperature/ humidity controller
He
H_2
Air
GC
Bypass line
Syringe pump
Temp controller
Sample chamber
Water bath

FIGURE 15.1
Experimental setup for breakthrough determination. (From Balanay, J.G et al. *Journal of Occupational and Environmental Hygiene* 11 (3): 133–143, 2014, reprinted by permission of The American Industrial Hygiene Association, www.aiha.org and The American Conference of Governmental Industrial Hygienists, www.acgih.org.)

15.3.1.4 Determination of Critical Bed Depth

Critical bed depth is the minimum adsorbent thickness required to obtain an acceptable chemical concentration at time zero and, thus, determines how thin a respirator can be made. In this study, critical bed depth was specifically defined as the minimum bed depth of the adsorbent that is required to reduce the challenge concentration of toluene by 90% or at $C_x/C_0 = 0.1$, wherein C_x is the effluent concentration and C_0 is the initial challenge concentration. The time in minutes when $C_x/C_0 = 0.1$ is referred to as the 10% breakthrough time, which was determined for each breakthrough curve at different adsorbent bed depths. The average time for duplicate breakthrough curves was calculated.

Per ACF type and challenge concentration, the 10% breakthrough times (min) obtained were plotted against the adsorbent bed depth (cm) to obtain a regression line. The bed depth at which the regression line intersects the x-axis was determined to be the critical bed depth, which was determined for each ACF type and challenge concentration of toluene (Watts, 1998). Thus, a total of six critical bed depths were obtained for each ACF type.

The standard error of the critical bed depth was calculated based on the standard error of the estimate (SE_y). The upper confidence limit of Y (UL_y) at 95% confidence level was calculated using the equation $UL_y = Y + t_3$ (SE_y), where $Y = 0$ and $t_3 = 3.182$. The projected upper confidence limit of X (UL_x) was then obtained using the equation $UL_x = (UL_y - b)/a$ where a is the slope of the line and b is the y-intercept. Finally, the standard error of X, and thus the critical bed depth, was calculated using the equation $SE_x = (UL_x - \text{CBD})/t_3$ where CBD is the critical bed depth (Daniel, 1991). SPSS version 20 software (SPSS Institute, Chicago, IL) was used to perform the standard error calculations.

15.3.1.5 Determination of Adsorption Capacity

Adsorption capacity is the amount of chemical adsorbed per mass of material and is used to determine the service life of the adsorbent. The time (min) when $C_x/C_0 = 0.5$ is referred to as the 50% breakthrough time, which was determined for each breakthrough curve at different adsorbent mass. The average time for duplicate breakthrough curves was calculated. Per ACF type and challenge concentration, the 50% breakthrough times (min) obtained were plotted against the adsorbent mass (g) to obtain a regression line for the calculation of the adsorption capacity (W_e) of each adsorbent at a certain concentration using the modified Wheeler equation (Jonas et al., 1973; Jonas et al., 1979), as shown below:

$$t_b = \frac{W_e}{C_0 Q}\left[W - \frac{\rho_B Q}{k_v}\ln(C_0 / C_x)\right] \tag{15.1}$$

wherein:

t_b—breakthrough time (min)
C_x—exit concentration (g/cm^3)
C_0—inlet concentration (g/cm^3)
Q—volumetric flow rate (cm^3/min)
W—weight of adsorbent (g)
ρ_B—bulk density of packed bed (g/cm^3)
k_v—first order rate constant of adsorption (min^{-1})
W_e—kinetic adsorption capacity (g/g)

Data at 50% breakthrough were chosen to determine the adsorption capacity to be more consistent throughout the experiment, since the lower (e.g., 10%) and the upper (100%) parts of the breakthrough curves have more variability in the breakthrough concentration data. The equation for calculating the adsorption capacity, $W_e = aC_0Q$, was derived and used to determine for each challenge concentration of toluene. Thus, a total of six adsorption capacities were obtained for each ACF type. The adsorption capacity (mg/g) was plotted against the challenge concentration to obtain the adsorption isotherms of each adsorbent for toluene.

Statistical analysis of the data was performed using the SPSS version 20 software (SPSS Institute, Chicago, IL). The standard error of the adsorption capacity was calculated based on the standard error of the slope.

15.3.1.6 Data Analysis

The critical bed depths and adsorption capacities of all the ACF types were compared according to ACF form and surface area using the analysis of covariance (ANCOVA). ANCOVA was performed to determine whether the critical bed depth or the adsorption capacity was significantly different among six ACF types when adjusted for toluene concentration. The critical bed depths in all challenge concentrations were pooled together for each ACF type to calculate the adjusted mean scores of the critical bed depth which were compared among the ACF types. The same analysis was done for the comparison of adsorption capacity among the ACF types.

Pairwise comparison of adsorption characteristics was also conducted between ACF types using independent (or one-way analysis of variance (ANOVA)) t-test. The comparison was done in three approaches: (1) between specific ACF types with different forms but similar surface areas, (2) between specific ACF types with same forms but different surface areas, and (3) between AC and AF in general.

For the comparison of specific ACFs, the critical bed depths or adsorption capacities at different concentrations were pooled for each ACF type. A total of 15 pairs were analyzed per adsorption characteristic but only nine pairs, as shown in Table 15.2, were of interest in this study. The α was calculated by 0.05 divided by the number of ACF types compared pairwise, which was $0.05/6 = 0.008$. For the comparison of AC and AF in general, the critical bed depths or adsorption capacities at different concentrations were pooled for each ACF form, with $\alpha = 0.05$.

TABLE 15.2

ACF Type Pairs Analyzed for Adsorption Characteristics Using Paired t-Test

Different Form/ Same Surface Area	**Same Form/Different Surface Area**	
AC10/AF10	AC10/AC15	AF10/AF15
AC15/AF15	AC10/AC20	AF10/AF18
AC20/AF18	AC15/AC20	AF15/AF18

Source: Balanay, J.G et al. *Journal of Occupational and Environmental Hygiene* 11 (3): 133–143, 2014, reprinted by permission of The American Industrial Hygiene Association, www.aiha.org and The American Conference of Governmental Industrial Hygienists, www.acgih.org

15.3.2 Results

15.3.2.1 ACF Form, Surface Area, and Porosity

The structural properties of each ACF type are summarized in Table 15.3, including weave type, thickness, density, and mass per depth. The nonwoven AF types are shown to be thicker than the woven AC types, and were less dense (0.05–0.06 g/cm^3) than the AC types (0.22–0.34 g/cm^3). Table 15.4 summarizes the surface characteristics of each ACF type, including the average surface area, micropore area, and pore size ($n = 3$). The results demonstrate that the measured surface area of the AC is similar to its AF counterpart (e.g., AC10 vs. AF10). Moreover, the AC20 has a measured surface area that is slightly higher than that of the AF18 but may still be comparable. Thus, AC20 and AF18 were considered as counterparts. The microporosity of the ACF materials was evidenced by the percentage of micropores by area, which is generally 80% or greater. Moreover, the average pore size of each ACF type was measured ranging from 1.67 to 1.84 nm (<2 nm), indicating microporosity.

For the AC types, as the surface area increases, the micropore area also increases, but the percentage of micropore by area decreases. This trend is not observed in AF types, which may imply that factors other than surface area affect the porosity of the materials. Furthermore, AC20 and AF18 have relatively close surface area but very different micropore area, which was much lower for AF18. This may be attributed to different precursors used in manufacturing of these ACFs, thus resulting in different pore structures.

15.3.2.2 Pore Size Distribution of ACF Materials

The pore size distribution of an adsorbent affects its adsorption capacity for molecules of various shapes and sizes, and is one of the criteria by which carbon adsorbents are selected for a specific application. The pore size of all the ACFs was measured to be less than 2.5 nm (Figure 15.2). For AC10, the

TABLE 15.3

ACF Structural Properties by ACF Type (Study Phase 1)

ACF Type	Weave Type	Thickness (cm)	Density[a] (g/cm^3)	Mass per Bed Depth[a] (g/cm)
AC10	Woven	0.063	0.34 ± 0.00	4.30 ± 0.05
AC15	Woven	0.063	0.28 ± 0.00	3.46 ± 0.06
AC20	Woven	0.063	0.22 ± 0.01	2.79 ± 0.07
AF10	Nonwoven	0.200	0.06 ± 0.00	0.75 ± 0.01
AF15	Nonwoven	0.300	0.06 ± 0.00	0.78 ± 0.02
AF18	Nonwoven	0.275	0.05 ± 0.00	0.68 ± 0.02

Source: Balanay, J.G et al. *Annals of Occupational Hygiene*, 2015, by permission of Oxford University Press.

[a] Mass of each ACF type was measured at four different bed depths.

TABLE 15.4

Average Surface Area, Micropore Area, and Pore Size by ACF Type ($n = 3$)

	Parameters			
ACF Type	Nominal Surface Area (m^2/g)	BET Surface Area (m^2/g)	Micropore Area[a] (m^2/g)	% Micropore by Area
AC10	1000	891.8 ± 7.8	840.2 ± 7.5	94.2 ± 0.6
AC15	1500	1470.8 ± 8.9	1336.9 ± 2.4	90.9 ± 0.5
AC20	2000	2052.8 ± 6.2	1726.7 ± 18.9	84.1 ± 0.7
AF10	1000	979.9 ± 19.0	876.8 ± 27.3	89.5 ± 1.3
AF15	1500	1407.3 ± 14.8	1277.9 ± 11.3	90.8 ± 0.2
AF18	1800	1861.1 ± 7.4	1041.8 ± 54.3	56.0 ± 3.1

Source: Balanay, J.G et al. *Journal of Occupational and Environmental Hygiene* 11(3): 133–143, 2014, reprinted by permission of The American Industrial Hygiene Association, www.aiha.org and The American Conference of Governmental Industrial Hygienists, www.acgih.org.

[a] By *t*-plot method.

majority of the micropores had a diameter at around 1 nm. AC15 had most of its micropores at around 0.9 nm but also had a secondary peak at around 1.2 nm. In addition to 0.9 nm-micropores, AC20 had smaller peaks from 1 to 2 nm. Thus, for the AC types, there was an increasing volume of larger micropores as the surface area increases. AF10 had mainly micropores distributed from 0.9 to 2 nm, and had a lower volume of micropores with 1 nm diameter. As the AF surface area increased (AF15 and AF18), the volume of micropores increased but the pore size range also widened. Comparing by ACF form, the AC types had greater volume of micropores with smaller diameters.

15.3.2.3 SEM Images

The images obtained from SEM analysis illustrated the fiber organization of the ACF materials. At 203× SEM magnification as shown in Figure 15.3 demonstrates that the inter-fiber structures of the cloth and felt forms (as represented by AC15 and AF15, respectively) were very different. The AC was composed of woven yarns of twisted fibers (Figure 15.3a), while the AF was composed of nonwoven, randomly distributed fibers (Figure 15.3b). Thus, this characteristic gave the AC approximately fivefold density of the AF.

15.3.2.4 Breakthrough Characteristics by ACF Form

The breakthrough curves show unique shapes for each ACF form. Figure 15.4 shows sample breakthrough curves representing AC (Figure 15.4a) and AF (Figure 15.4b) types at 500 ppm toluene and at four different bed depths by number of layers. With AC, the increase in toluene concentration occurred slowly from the breakpoint. Such gradual increase was more prominent as

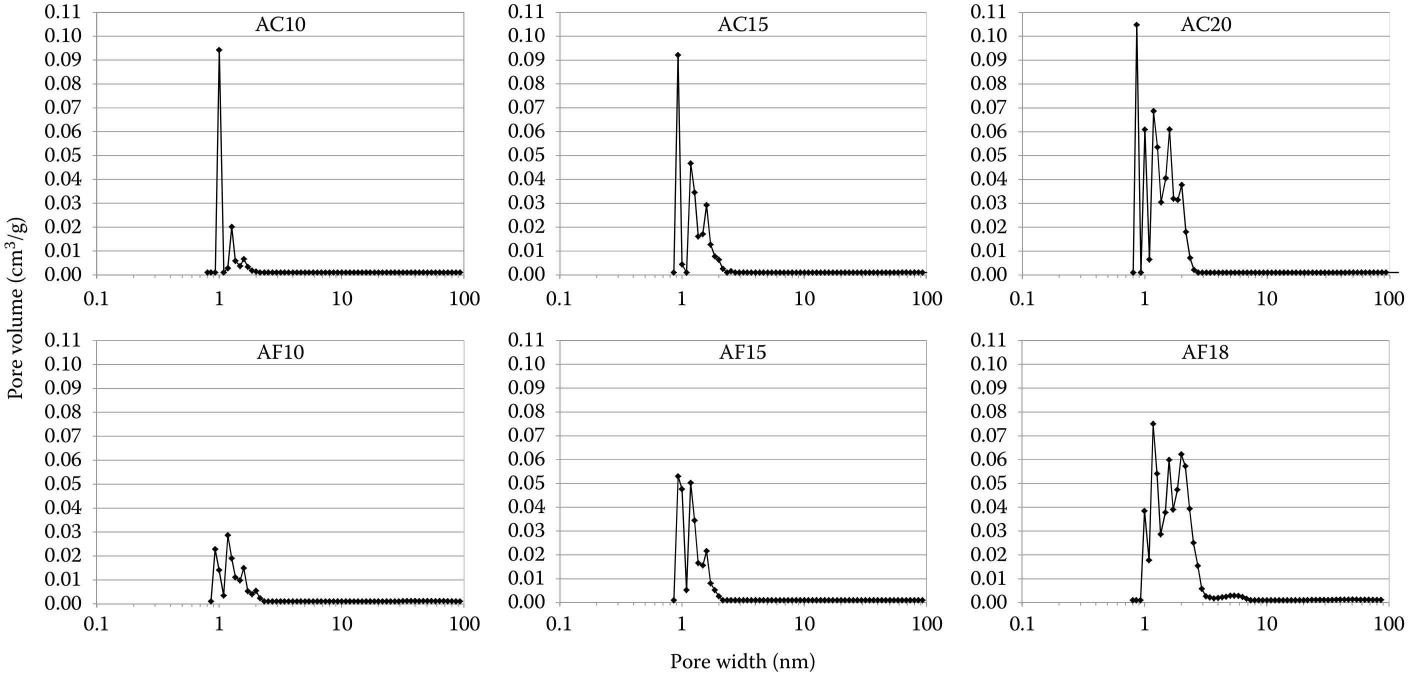

FIGURE 15.2
Pore size distribution of ACF types. (From Balanay, J.G et al. *Journal of Occupational and Environmental Hygiene* 11 (3): 133–143, 2014, reprinted by permission of The American Industrial Hygiene Association, www.aiha.org and The American Conference of Governmental Industrial Hygienists, www.acgih.org.)

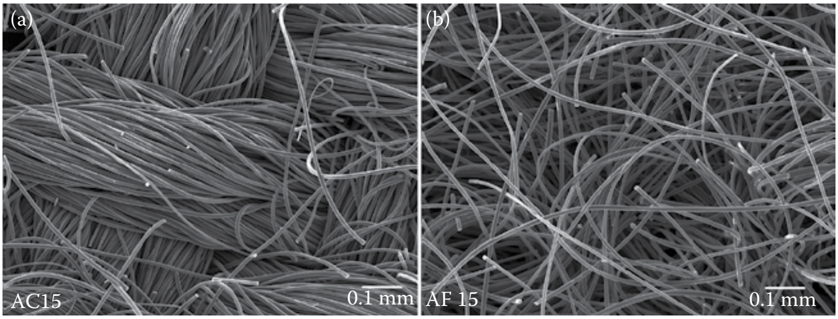

FIGURE 15.3
SEM images of (a) AC15 and (b) AF15 at ×203 magnifications. (From Balanay, J.G et al. *Annals of Occupational Hygiene*, 2015, by permission of Oxford University Press.)

the number of adsorbent layers increased. With AF, the increase in toluene concentration occurred abruptly from the time the breakpoint started. However, the increase in concentration slowed down as 100% breakthrough was approached. This trend became more prominent as the challenge concentration decreased.

When comparing AC and AF with similar specific surface areas at the same number of layers, it took a shorter time for toluene to approach near saturation (i.e., $C/C_0 = 0.90$) from the start of the breakpoint with AF compared to AC, as demonstrated by the steeper slope of the breakthrough curves for AF. The gradual increase in the effluent concentration for AC, particularly at higher number of layers, suggests a larger mass transfer resistance and a layering effect for AC. In contrast, the abrupt increase in the effluent concentration at the breakpoint for AF indicates that the micropores across the bed depth were equally available and filled simultaneously, demonstrating the lack of layering effect for AF. These observations may be attributed to the difference in fiber density between the cloth and felt. As shown in the SEM images, the AC had

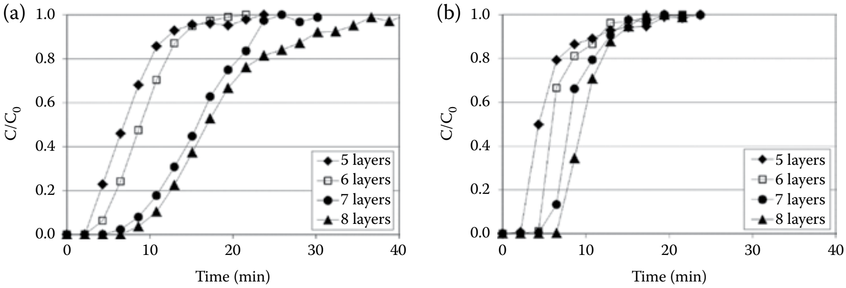

FIGURE 15.4
Experimental breakthrough curves for (a) AC10 and (b) AF10 by number of layers at $C_0 = 500$ ppm toluene. (From Balanay, J.G et al. *Annals of Occupational Hygiene*, 2015 by permission of Oxford University Press.)

tightly woven fibers and was denser than the AF, which had loosely packed fibers that were distributed randomly. Because of the AF's lower density and looser packing, each fiber within the adsorbent bed was more equally available for diffusive adsorption of contaminants from the air flow and adsorbent loads nearly uniformly. Conversely, in the AC, the tight, organized weaving of the cloth caused more interaction between the fibers and air flow, allowing each fiber more opportunity to remove contaminants on a single pass. As the adsorbent bed approached saturation, the downstream layers were less saturated than the upstream layers, and it took time for the remaining layers to reach full saturation, as demonstrated by the slower increase to near saturation after the breakpoint (Figure 15.4).

15.3.2.5 Effect of Toluene Concentration on Breakthrough Characteristics

The effect of toluene concentration on the breakthrough characteristics of AC and AF is shown in Figure 15.5 for a fixed bed depth (five layers of ACF). The trends in this data were represented by AC15 and AF15. The breakthrough time of toluene through a fixed number of ACF layers increased as the toluene challenge concentration decreased, as expected. However, such increase in breakthrough time is not linear with the concentration. Greater increase in breakthrough time at the lower concentrations compared to that at higher concentrations was observed with the same proportional change in challenge concentration, as was evidenced by the nonlinear trends shown in Figure 15.6. The steepness of the breakthrough curves (Figure 15.5) increased with toluene concentration, demonstrating decreasing saturation times. The increase in both the breakthrough and saturation times with the decrease in toluene challenge concentration indicates a longer service life for ACF at lower toluene concentrations. The uncharacteristic curve shapes of AF15, particularly at 50 ppm toluene (Figure 15.5b), is not fully understood at this time, but is suspected to be due to the low bulk density of the AF material,

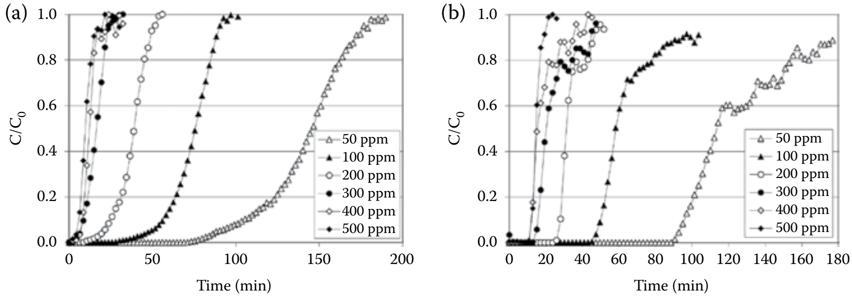

FIGURE 15.5
Experimental breakthrough curves for (a) AC15 and (b) AF15 by toluene concentration at number of ACF layers = 5. (From Balanay, J.G et al. *Annals of Occupational Hygiene*, 2015, by permission of Oxford University Press.)

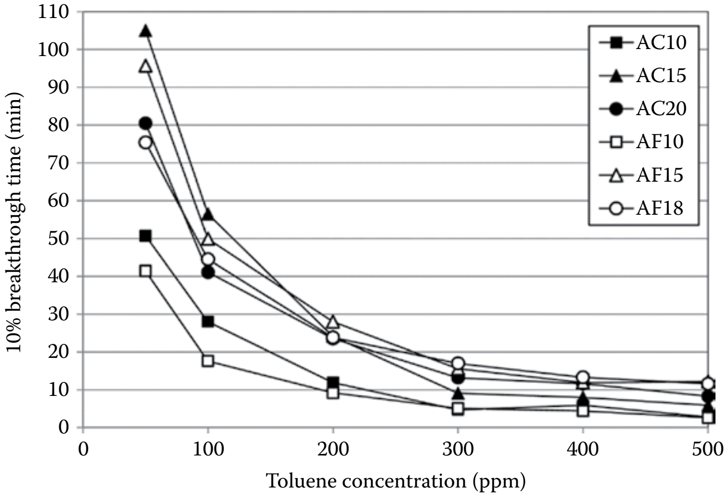

FIGURE 15.6
10% Breakthrough time as a function of toluene concentration by ACF type at number of ACF layers = 5. (From Balanay, J.G et al. *Annals of Occupational Hygiene*, 2015, by permission of Oxford University Press.)

given its "spongier" characteristic compared to the AC type. The AF structure may have allowed toluene molecules to readily penetrate through the AF bed nonuniformly, without fully saturating each layer. At a low concentration, certain regions in the material becomes completely saturated, subsequently allowing the toluene molecules to travel through the regions still holding some unspent capacity. Thus, the breakthrough curve is sharp as penetration starts but becomes elongated as certain regions in the material slowly become saturated.

15.3.2.6 10% Breakthrough Time

The 10% breakthrough times were compared among ACF types at a given bed depth, with the purpose of characterizing the potential respiratory protection against airborne toluene at different concentrations for each ACF type (Figure 15.7). Given that the wearer's breathing results in a face velocity similar to that in the test condition (i.e., 0.21 m/sec), at an adsorbent bed depth = 0.5 cm and surface area = 12.6 cm^2 (based on the 4-cm ACF discs), using ACs in a respirator may afford protection to the wearer from 11 to 19 min before 10% breakthrough of 500 ppm toluene occurs, and from 134 to 190 min for 50 ppm toluene. AFs in a respirator at an adsorbent bed depth = 1.5 cm and surface area = 12.6 cm^2 may afford protection to the wearer from 3 to 15 min before 10% breakthrough of 500 ppm toluene occurs, and from 41 to 96 min for 50 ppm toluene. If the area of the ACF adsorbent is increased to that of a typical small-size N95 respirator (approximately

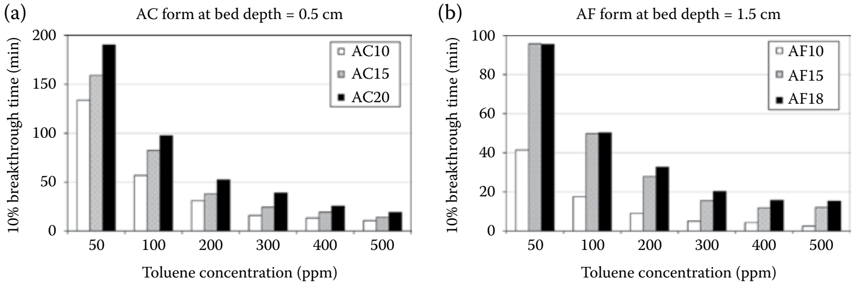

FIGURE 15.7
10% Breakthrough time of toluene by ACF type: (a) AC form and (b) AF form. (From Balanay, J.G et al. *Annals of Occupational Hygiene*, 2015, by permission of Oxford University Press.)

165 cm^2), such ACF respirator may provide approximately 13 times longer performance if the adsorbent bed depth and air velocity through the adsorbent are the same as in these tests and if there is uniform adsorption throughout the entire respirator. This would mean that AC may provide 143–247 min of respiratory protection at 500 ppm toluene and 1742–2470 min at 50 ppm toluene, while AF may afford protection from 39–195 min at 500 ppm toluene and 533–1248 min at 50 ppm toluene. For each concentration, the 10% breakthrough time generally increased as the ACF specific surface area increased (Figure 15.7), which may be attributed to the increasing micropore volume.

Breakthrough times of toluene as a function of bed depth are shown for the various ACF types at two different concentrations (Figure 15.8). The bed depth tested for AC ranged from 0.25 to 0.50 cm (4 to 8 layers) and for AF ranged from 0.83 to 2.10 cm (3 to 8 layers). Given the same bed depth, AC types exhibit a higher breakthrough time compared to AF, as illustrated with the 50 and 500 ppm toluene trials shown in Figure 15.8. This can be attributed to the more dense form of AC than AF, as described earlier. Thus, for

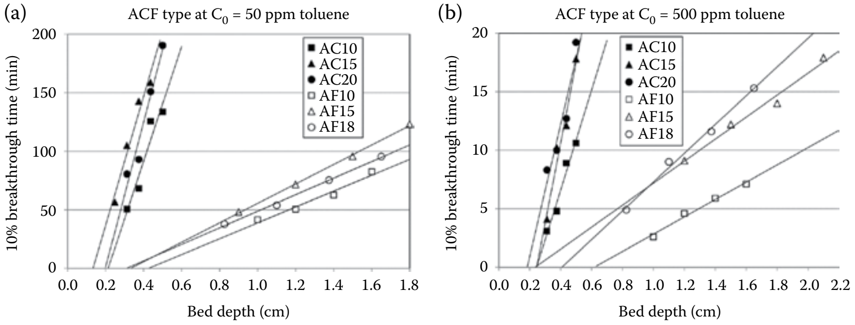

FIGURE 15.8
10% Breakthrough time of toluene as a function of bed depth by ACF type at (a) $C_0 = 50$ ppm and (b) 500 ppm. (From Balanay, J.G et al. *Annals of Occupational Hygiene*, 2015, by permission of Oxford University Press.)

an equivalent studied bed depth, the mass of AC is higher than the mass of AF, as shown in Table 15.3. Consequently, as breakthrough time increases with the bed depth, the rate of increase is higher for AC than for AF. The ACF with the lowest specific surface area, either cloth (i.e., AC10) or felt (i.e., AF10) form, had the lowest breakthrough time at a given bed depth for both toluene concentrations.

Figure 15.9 shows the toluene breakthrough times of ACF types as a function of adsorbent mass at two concentrations, which demonstrates varying performance of AC versus AF types. Given the same mass (e.g., 1.5 g), all AF types showed higher breakthrough times compared to the AC types at 500 ppm toluene, while AC types of higher specific surface area (AC15 and AC20) showed higher breakthrough times compared to their AF counterparts (AF15 and AF18) at 50 ppm toluene. Interestingly at 50 ppm toluene, AC10 exhibited a higher breakthrough time than AF10 when adsorbent mass reached 2.1 g. However, bed depth was given more emphasis in this study than adsorbent mass because there are practical limitations to how thick a respirator cartridge or N95-like mask could be without impeding the wearer's vision or comfort.

15.3.2.7 Critical Bed Depth

Figure 15.10 shows the critical bed depths of the three AC and three AF types, respectively, for different toluene challenge concentrations. These graphs show that the ACF with the lowest surface area had the highest critical bed depth, ranging from 0.18 to 0.25 cm for AC and 0.32 to 0.64 cm for AF. Among the ACF types, AC15 and AC20 (2 highest surface areas) had the lowest critical bed depths (0.110–0.164 cm and 0.111–0.219 cm, respectively) for each toluene concentration, making them good candidates for thinner respirators.

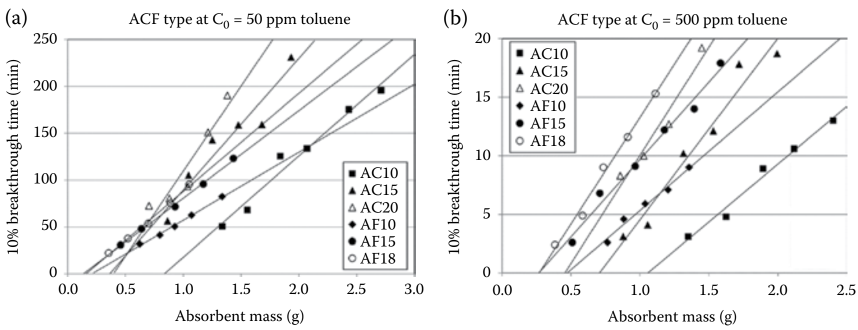

FIGURE 15.9
10% Breakthrough time of toluene as a function of mass by ACF type at (a) $C_0 = 50$ ppm and (b) 500 ppm. (From Balanay, J.G et al. *Annals of Occupational Hygiene*, 2015, by permission of Oxford University Press.)

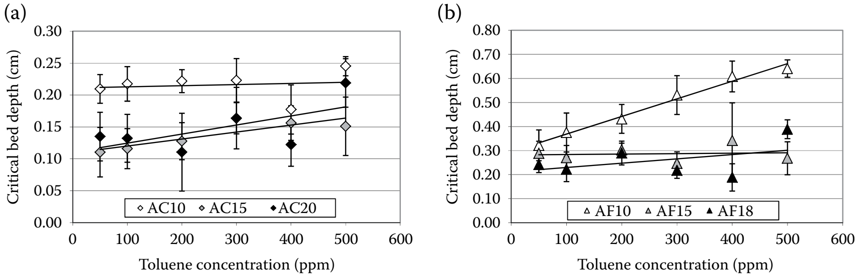

FIGURE 15.10
Critical bed depth by ACF type at different toluene concentrations. (a) AC type and (b) AF type. (From Balanay, J.G et al. *Journal of Occupational and Environmental Hygiene* 11 (3): 133–143, 2014, reprinted by permission of The American Industrial Hygiene Association, www.aiha.org and The American Conference of Governmental Industrial Hygienists, www.acgih.org.)

Figure 15.11 shows the mean critical bed depths of all the ACF types tested according to form and surface area. The cloth and felt with similar surface areas were compared to determine if the form of the ACF influenced the critical bed depth. The mean critical bed depth of the AC form was significantly lower ($P < 0.001$–0.004; $\alpha = 0.008$) compared to the AF form of similar surface area. The difference between the overall mean critical bed depth of AC (167 ± 0.045 cm) and that of AF (0.343 ± 0.132 cm) was statistically significant ($P < 0.01$; $\alpha = 0.05$).

Moreover, the cloth or felt forms with different surface areas were compared against each other to determine the influence of ACF surface area to the critical bed depth. For AC types, the critical bed depth of AC10 (lowest surface area) was significantly higher ($P = 0.002$; $\alpha = 0.008$) than those of

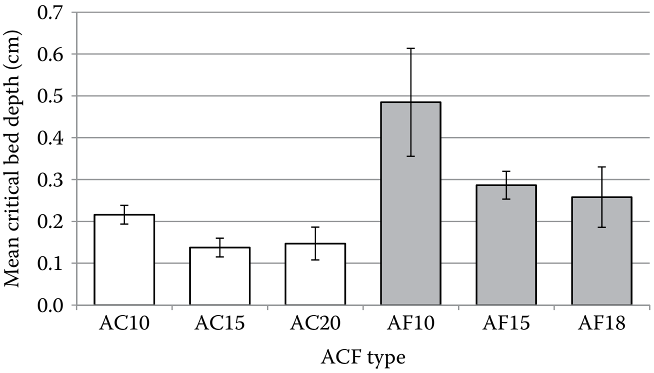

FIGURE 15.11
Mean critical bed depth by ACF type. (From Balanay, J.G et al. *Journal of Occupational and Environmental Hygiene* 11 (3): 133–143, 2014, reprinted by permission of The American Industrial Hygiene Association, www.aiha.org and The American Conference of Governmental Industrial Hygienists, www.acgih.org.)

AC15 and AC20. However, the critical bed depths of AC15 and AC20 were not significantly different ($P = 0.536$). For AF types, only the critical bed depths of AF10 and AF18 were significantly different ($P = 0.007$; $\alpha = 0.008$).

15.3.2.8 Adsorption Capacity

Figure 15.12 shows the adsorption capacities of the three AC and three AF types for different toluene challenge concentrations. The adsorption capacity had an increasing trend as the surface area increased for both AC and AF types. The AC generally had higher adsorption capacities (ranging from 345 to 878 mg/g) compared to the AF (ranging from 221 to 616 mg/g). Among the ACF types, AC20 (highest surface area) had the highest adsorption capacity (ranging from 595 to 878 mg/g) for each toluene concentration.

The adsorption capacities of all the ACF types tested were compared according to form and surface area (Figure 15.13), demonstrating an increasing trend as the ACF surface area increased. The cloth and felt with similar surface areas were compared to determine the influence of ACF form on the adsorption capacity. The mean adsorption capacity of the AC form was significantly higher ($P < 0.001$–0.001; $\alpha = 0.008$) compared to the AF form with similar surface area. The difference between the overall mean adsorption capacity of AC (522.7 ± 158.7 mg/g) and that of AF (377.7 ± 90.9 mg/g) was statistically significant ($P < 0.01$, $\alpha = 0.05$).

Furthermore, the cloth or felt forms with different surface areas were compared to determine if the surface area of the ACF influences the adsorption capacity. For AC types, the adsorption capacities between all three AC pairs with different surface areas were significantly different ($P < 0.001$–0.002; $\alpha = 0.0080$), such that the AC with higher surface area had a significantly higher adsorption capacity. For AF pairs, only the difference in adsorption capacities between AF15 and AF18 (highest two surface areas) was not significant ($P = 0.032$; $\alpha = 0.008$).

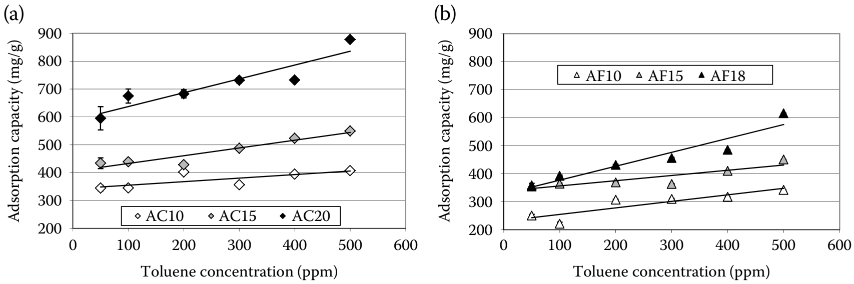

FIGURE 15.12

Adsorption capacity by ACF type at different toluene concentrations. (a) AC type and (b) AF type. (From Balanay, JG et al. *Journal of Occupational and Environmental Hygiene* 11 (3): 133–143, 2014, reprinted by permission of The American Industrial Hygiene Association, www.aiha.org and The American Conference of Governmental Industrial Hygienists, www.acgih.org.)

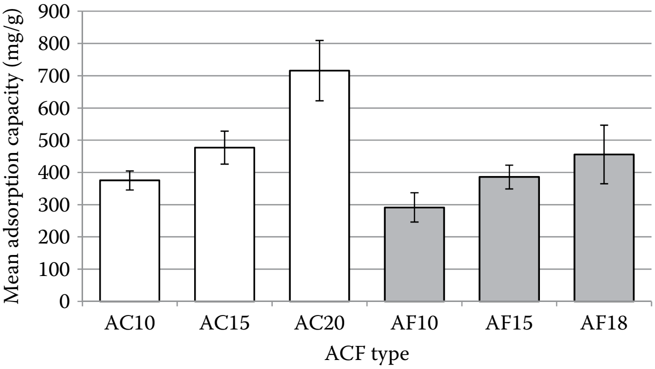

FIGURE 15.13
Mean adsorption capacity by ACF type. (From Balanay, J.G et al. *Journal of Occupational and Environmental Hygiene* 11 (3): 133–143, 2014, reprinted by permission of The American Industrial Hygiene Association, www.aiha.org and The American Conference of Governmental Industrial Hygienists, www.acgih.org.)

15.3.3 Discussion

15.3.3.1 Influence of ACF Surface Area and Form on Critical Bed Depth

Critical bed depth is defined in this study as the minimum bed depth of the adsorbent required to reduce the concentration of toluene by 90%. The lower the critical bed depth, the better the adsorbent because it takes a smaller depth of the material to prevent the penetration of a certain amount of chemical, and thus may make a thinner respirator. Regardless of form, the ACF with the lowest surface area had the highest critical bed depth, which was significantly different from those of ACF with the highest surface area. This may be explained by the amount of available adsorption sites at a given ACF thickness, which was evidently less in low-surface area ACFs. Thus, AC10 and AF10 need more materials to adsorb a particular amount of toluene. For each ACF form, the two ACFs with the highest surface areas (AC15 vs. AC20; AF15 vs. AF18) did not have significantly different mean critical bed depths. Apparently, the critical bed depth is dependent on the surface area only to a certain extent because further increase in surface area did not seem to significantly decrease the critical bed depth further. On the other hand, the critical bed depth was shown to increase as the challenge toluene concentration increased, which was more pronounced with AF10. This trend may be explained by the amount of material required to adsorb a certain amount of toluene. At higher concentration, more ACF material was needed to adsorb more toluene molecules present in the atmosphere.

The AC had a lower critical bed depth compared to that of the AF with similar surface area per toluene concentration. When pooled at all concentrations, the mean critical bed depth of an AC type was significantly lower than that of its AF counterpart. Overall, AC still had a significantly lower critical bed depth compared to AF because an AC layer was thinner and denser than an AF layer, which was more spongy in nature. As AF was thicker than its AC counterpart at similar surface area, its density was lower than that of AC. Thus, AC had more mass per bed depth, which entails more fibers and more surface area for adsorption. The critical bed depth, therefore, depended on the physical form of the ACF and is mainly affected by the density and thickness of the material. Based on the critical bed depth, the AC15 and AC20 were the best adsorbents because they had the smallest critical bed depths for each toluene concentration, making them good candidates for the development of thinner respirators.

15.3.3.2 Influence of ACF Surface Area and Form on Adsorption Capacity

Adsorption capacity is the maximum amount of substance adsorbed by a material per unit mass. The higher the adsorption capacity, the better the adsorbent is because it captures more chemicals at a certain amount of material. Adsorption capacity increased as the toluene challenge concentration increased for all of the ACF types. This trend is common in adsorbent materials and is typically demonstrated in an adsorption isotherm. The greater the adsorbate concentration, the greater the relative pressure, and the more molecules are pressed onto the adsorbent surface.

The adsorption capacity had an increasing trend as the surface area increases for both AC and AF types. This can be explained by the amount of available adsorption sites for toluene molecules at a given ACF mass, which was expectedly greater in high-surface area ACFs. Previous studies have demonstrated similar results for other VOCs, wherein a linear relationship was found between the adsorption capacities of organic compounds and the surface areas of adsorbents, independent of the type of adsorbent (Tanada et al., 2000; Zhang et al., 2010). A study by Tanada et al. (2000) investigated on the adsorption of nonafluorobutyl methyl ether (NFE) onto ACF and demonstrated that the increasing specific surface area increased the adsorption capacity to NFE.

ACF of the same forms but with different surface areas had significantly different mean adsorption capacity, except for AF15 (386 mg/g) when compared to AF18 (456 mg/g). AF18 had a higher BET surface area than AF15, but had a lower micropore area and percentage of micropores. With the adsorption capacity of AF18 being higher than that of AF15 but not significantly different, it is implied that surface area may affect the adsorption capacity of the ACF but the microporosity of the material also has an influence. With AF18 having more wider pores (i.e., mesopores) compared to AF15, the amount of adsorption was effectively lowered due to less overlap of attractive forces in opposite pore walls in mesopores, as compared to the adsorption in micropores. The difference in microporosity between the AF15 and AF18 may be influenced by the type of precursor fiber used and the manufacturing processes (i.e., duration and type of activation) performed on these adsorbents since these factors have strong influences on the porous structure and adsorption properties of the resulting adsorbents (Ryu et al., 2000). If the amount of micropores in these two AFs were similar, the adsorption capacity of AF18 could have been higher than the AF15. Therefore, the surface area may be considered a determinant of adsorption capacity for toluene, but the microporosity of the ACF can also be influential.

The AC generally had significantly higher mean adsorption capacities compared to the AF. Specifically, an AC type also had a significantly higher mean adsorption capacity when compared to the AF with similar surface area. This may be explained by the difference in their micropore size distribution. The AC had micropores of smaller diameter, resulting in greater adsorption energies within these micropores. This shows the importance of the development of narrow microporosity of adsorbents in order to optimize toluene adsorption at low concentration, as shown in previous studies. One study found that the amount adsorbed at low adsorbate concentrations depends on the pore size distribution of the sample, particularly its microporosity (Fuertes et al., 2003). In turn, the difference in micropore size distribution may be attributed to the density of the ACF and the accessibility of the fiber surface to the activating gas during the activation process. Since the AC has tightly woven fibers compared to the AF, some of its fiber surfaces are less accessible to the activating gas that etches away the pores, resulting in pore widening and decrease in the volume of smaller micropores. Therefore, the adsorption capacity depends on the physical form of the ACF.

Adsorption capacity was demonstrated to be dependent on both the surface area and physical form of the ACF. The ACF with the highest surface area had the highest adsorption capacity per ACF form. The AC had a higher adsorption capacity than the AF at all toluene concentrations. Based on the adsorption capacity, AC20 was the best adsorbent because it had the highest adsorption capacity across all toluene concentrations.

15.3.3.3 Application of ACF Adsorption Characteristics to Respiratory Protection

The extent of respiratory protection that the studied ACF types may provide against airborne contaminants may be described based on their breakthrough characteristics. Both breakthrough and saturation times increased as toluene challenge concentration decreased, indicating a longer service life for ACF at lower toluene concentrations. At 50 ppm toluene, an N95-like ACF respirator composed of a 0.5-cm AC may have a service life of at least 28 hours, and one composed of a 1.5-cm AF may have a service life of at least 8 hours. At the OSHA PEL of 200 ppm, the AC may provide protection against toluene for at least 6 hours, and AF for at least 2 hours. Protection afforded by ACF respirators against toluene at higher concentrations will last for a shorter period. At 500 ppm, the IDLH for toluene, the same N95-like AC respirator may provide protection for at least 140 minutes, while the AF respirator for at least 30 minutes, given a face velocity and relative humidity similar to the test condition. Thus, some of these ACF types may be suitable for emergency purposes, such as escaping from an area with high-volume spills resulting in high ambient concentration of toluene. However, in an emergency situation, breathing rates are expected to be higher than normal use conditions due to panic and/or high levels of physical exertion, which is expected to decrease the protection time during escape scenarios. From a safety standpoint, ACF is indicated to be more suitable for use at lower ambient concentrations in providing longer respiratory protection against toluene. However, increasing the bed depth of these ACF materials in respirators should provide longer protection against toluene.

It is important to note that the service lives identified for the N95-like ACF respirators were based on 10% breakthrough of challenge toluene concentrations. Certain respirator certification assessments for organic vapor service life may have used a lower percentage breakthrough, such as 0.5% of 1000 ppm carbon tetrachloride in NIOSH testing (NIOSH, 2006). Testing the ACF respirators using these certification conditions or criteria may result in shorter service lives, and thus shorter protection times. Moreover, ACF materials were tested in this study using a constant unidirectional airflow, humidity, and temperature. In realistic workplace scenarios, ACF respirators are exposed to bi-directional airflow and humidity fluctuations due to worker breathing and thus, respirator service lives may change. Breakthrough times have been demonstrated to significantly decrease when airflow across activated carbon adsorbents was changed from fixed flow to sinusoidal flow (Suzin et al., 2000; Nir et al., 2002; Linders et al., 2003). The effect of sinusoidal airflow on toluene adsorption onto ACF respirators needs further investigation to determine the extent of decrease in breakthrough times.

In addition to the breakthrough characteristics, the assessment of the potential of ACF for use in respiratory protection may also be based on the critical bed depth and adsorption capacity. Based on these two adsorption characteristics, the AC form with the highest surface area (i.e., AC20 and AC15) was demonstrated to be the best adsorbent candidate for the development of thinner and efficient respirators against toluene because it has both the lowest critical bed and the highest adsorption capacity. However, pressure drop across the respirator is another important factor to consider and is one of the requirements tested by NIOSH for respirator use approval. This can be a concern for AC types because they are much denser than the AF due to their tightly woven fibers that may restrict airflow. To further investigate the possible application of ACFs in respiratory protection, the need to study the pressure drop across ACFs in actual respirator cartridges or filters was identified to determine the optimum dimensions (i.e., thickness) and density of ACF materials that will result in acceptably breathable respirators. Thus, the next phase of our ACF study was conducted with this purpose.

15.4 Study Phase 2: Determination of Pressure Drop

Pressure drop is defined as the difference in static pressure between two pressure points located before and after an air-cleaning media, which is a function of flow rate and face velocity. Pressure drop is equivalent to breathing resistance when applied to respiratory protection. The static pressure point downstream of the media is lower than the static pressure point upstream, resulting in a drop in pressure. Pressure drop may be translated into the breathability of a respirator. Thus, it is important for respirators to have pressure drop as low as possible, since it has been shown that increasing inhalation and exhalation resistances across respirators decrease workers' performance (Caretti et al., 2006). Pressure drop across ACFs assembled as a filter in air treatment devices has been previous studied (Hayashi et al., 2000; Subrenat et al., 2000), but not as an adsorbent for respirators. Moreover, one of the NIOSH requirements for respirator certification is on breathing resistance. NIOSH has standard testing procedures (STPs) for determining both inhalation and exhalation breathing resistances for air-purifying respirators. For chemical cartridge respirators other than single-use vinyl chloride respirators, the maximum allowable resistance requirement is 20 mmH_2O for exhalation resistance (NIOSH, 2014a), and 40 mmH_2O for inhalation (NIOSH, 2014b).

As shown in Phase 1 of the study, ACFs have great potential for the development of lighter and more efficient respirators for airborne contaminants due to their high adsorption capacities and low critical bed depth. The service life of ACF respirator cartridges may be further extended by increasing the thickness or density of the adsorbent in the cartridge. However, this may lead to an increased resistance to air flow and a greater physiological burden on the respirator user. To optimize the ACF cartridge configuration, it is crucial to determine how the composition and density of the ACF materials in cartridges affect breathing resistance. The purpose of this study phase was to determine and compare the pressure drop across different types of ACFs in realistic respirator cartridges using constant airflow. The main goal was to develop ACF cartridge configurations that have acceptable breathing resistance according to NIOSH certification requirements.

15.4.1 Methodology

15.4.1.1 Materials

Two forms of commercially available ACF were used as adsorbent materials: woven cloth (AC, one type) and nonwoven felt (AF, six types), for a total of seven types of ACFs tested. The ACFs were obtained from American Technical Trading, Inc. (Pleasantville, NY) and were manufactured from novoloid, a phenol aldehyde-based fiber. Table 15.5 shows the designation for each ACF type and their corresponding structural properties, including thickness and density. The thickness of the AC is 0.11 cm and that of the AF types range from 0.23 to 0.50 cm, which is more than twice greater than that of the AC. However, the AF types were less dense (0.041–0.070 g/cm^3) than the AC (0.101 g/cm^3), giving the AF a spongier characteristic. The ACFs were cut into 3-inch diameter discs, with a diameter similar to that of a typical respirator cartridge container. The ACF discs were thermally treated in a Precision Compact Model 665 oven (Thermo Scientific, Marietta, OH) at 200°C overnight prior to testing to desorb any volatile impurities and remove excess moisture on the adsorbent materials. After oven treatment, the ACF discs were weighed (in grams) using a Voyager Pro analytical balance (Ohaus Corp., Parsippany, NJ), and the thickness (in cm) was measured using a Vernier caliper. The ACF discs were then placed in a respirator cartridge (3-inch internal diameter, 1-inch depth) for pressure drop testing. GAC in an organic vapor cartridge (Willson, Reading, PA) was also tested in this study for comparison. The GAC was thermally treated, weighed, and placed in a cartridge similarly as the ACF materials prior to pressure drop testing.

15.4.1.2 Scanning Electron Microscopy

The organization and morphology of the ACF's individual fibers, particularly the weaving tightness, was examined using a scanning electron microscope (SEM). SEM images of the ACFs were obtained at three magnifications (50×, 200×, and 800×) to visualize the fiber arrangement in ACF samples.

TABLE 15.5

ACF Structural Properties by ACF Type (Study Phase 2)

ACF Type	Weave Type	Thickness (cm)[a]	Density (g/cm^3)
ACFC	Woven	0.11	0.101
ACFF1	Nonwoven	0.23	0.043
ACFF2	Nonwoven	0.29	0.069
ACFF3	Nonwoven	0.29	0.057
ACFF4	Nonwoven	0.24	0.043
ACFF5	Nonwoven	0.30	0.041
ACFF6	Nonwoven	0.50	0.070

Source: Balanay, J.G. and C.T. Lungu: *Journal of Occupational and Environmental Hygiene*, 13 (2): 141–147, 2016, reprinted by permission of The American Industrial Hygiene Association, www.aiha.org and The American Conference of Governmental Industrial Hygienists, www.acgih.org.

[a] Average of two samples ($n = 2$).

15.4.1.3 Pressure Drop Determination

Respirator cartridges were filled with ACF materials of varying composition and were designated based on the ACF composition and densities (Tables 15.6 and 15.7). Table 15.6 shows single-ACF type cartridges that are composed of 100% of a specific ACF type. CS1, CS2, and CS3 cartridges contain the same ACF type (AF1) but its density was increased by increasing the number of layers (9, 10, and 11 layers, respectively) compressed in the cartridge. Table 15.7 shows the combination-ACF type cartridges that are composed of two ACF types, with percentage by weight for each ACF type indicated. Polypropylene sheets (Pall Life Sciences, Port Washington, NY) cut into 3-inch diameter discs were placed on both outer sides such that the ACF discs were sandwiched between the polypropylene sheets, which were intended to prevent the inhalation of carbon particulates from the ACF cartridge when used in a respirator.

The ACF cartridge was placed in a customized cylindrical Teflon chamber (6 inches in internal diameter, 12 inches in length) and challenged with preconditioned air at a constant airflow (43 LPM), temperature (23°C), and relative humidity (50%). The cartridge tested in this study is usually used in pairs in a dual cartridge respirator, with each cartridge receiving half of the total airflow. Since a single cartridge was tested at a time, the flow rate used in this study was approximately half of the constant airflow (85 LPM) used by NIOSH in testing the breathing resistance of respirator chemical cartridges

TABLE 15.6

ACF Composition and Average Pressure Drop and Weight ($n = 3$) of Single-ACF Type Cartridges

Cartridge Designation	ACF Composition	Pressure Drop, mmH_2O (mean ± SD)	Weight, g (mean ± SD)
CS1	100% AF1 (density 1)	23.71 ± 0.64	4.24 ± 0.11
CS2	100% AF1 (density 2)	26.83 ± 0.67	4.67 ± 0.09
CS3	100% AF1 (density 3)	29.95 ± 0.26	5.09 ± 0.03
CS4	100% AF2	31.73 ± 0.91	7.49 ± 0.27
CS5	100% AF3	35.94 ± 0.22	5.89 ± 0.30
CS6	100% AF4	36.70 ± 0.39	4.57 ± 0.08
CS7	100% AF5	37.40 ± 1.29	4.78 ± 0.09
CS8	100% AF6	39.93 ± 0.67	9.17 ± 0.23
CS9	100% AC	85.47 ± 3.67	14.00 ± 0.22
GAC	100% GAC[a]	23.13 ± 1.14	60.34 ± 0.10

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[a] Composed of GAC for comparison with ACF.

TABLE 15.7

ACF Composition and Average Pressure Drop and Weight ($n = 3$) of Combination-ACF Type Cartridges

Cartridge Designation	ACF Composition by % Weight	Pressure Drop, mmH_2O (mean ± SD)	Weight, g (mean ± SD)
CC1	70% AF1/30% AC	28.91 ± 0.14	5.50 ± 0.17
CC2	80% AF1/20% AC	31.06 ± 0.43	6.47 ± 0.12
CC3	67% AF1/33% AF6	32.81 ± 1.53	5.51 ± 0.20
CC4	43% AF1/57% AF6	27.56 ± 2.42	5.68 ± 0.31
CC5	40% AF1/60% AF2	27.47 ± 0.70	5.84 ± 0.07
CC6	30% AF1/70% AF2	27.39 ± 0.42	6.29 ± 0.34
CC7	20% AF1/80% AF2	28.55 ± 1.13	6.78 ± 0.36
CC8	44% AF1/56% AF3	30.76 ± 0.26	5.01 ± 0.17
CC9	54% AF1/ 46% AF3	30.08 ± 0.73	5.03 ± 0.12
CC10	68% AF1/32% AF3	28.33 ± 0.25	4.79 ± 0.01
CC11	50% AF1/50% AF4	29.52 ± 0.67	4.87 ± 0.08
CC12	60% AF1/40% AF4	30.35 ± 0.80	4.90 ± 0.02
CC13	69% AF1/31% AF4	30.17 ± 0.41	5.03 ± 0.34
CC14	61% AF1/39% AF5	29.75 ± 0.68	4.98 ± 0.49
CC15	50% AF1/50% AF5	29.86 ± 0.70	4.81 ± 0.21
GAC	100% GAC[a]	23.13 ± 1.14	60.34 ± 0.10

Source: Balanay, J.G. and C.T. Lungu: *Journal of Occupational and Environmental Hygiene*, 13 (2): 141–147, 2016, reprinted by permission of The American Industrial Hygiene Association, www.aiha.org and The American Conference of Governmental Industrial Hygienists, www.acgih.org.

[a] Composed of GAC for comparison with ACF.

for certification (NIOSH, 2014a,b). Clean, dry air was supplied by an air compressor equipped with air filtering units (Parker Hannifin Corp., Haverhill, MA), and controlled at constant temperature, relative humidity, and flow rate using a Miller-Nelson Model HCS-501–100 instrument (Assay Technology, Livermore, CA). A reagent-grade water purification system (Aqua Solutions, Inc., Jasper, GA) was used to supply purified water to the Miller-Nelson unit for relative humidity control. The temperature and relative humidity in the test chamber were monitored using a HOBO Model U14–002 temperature and relative humidity datalogger (Onset Computer Corp., Pocasset, MA). Pressure drop (in mmH_2O) across the ACF cartridges was measured and logged using a DP-Calc Model 5825 micromanometer (TSI Inc., Shoreview, MN). Pressure drop measurements across each ACF cartridge were obtained every 30 seconds for 20 minutes, resulting in a total of 40 pressure drop data points per test. The average pressure drop was calculated per test. Each test was conducted in triplicates. The instruments and materials were set up in such a way that the direction of airflow was toward the outer (i.e., inlet) side of the cartridge, thus representing the inhalation pressure drop across the

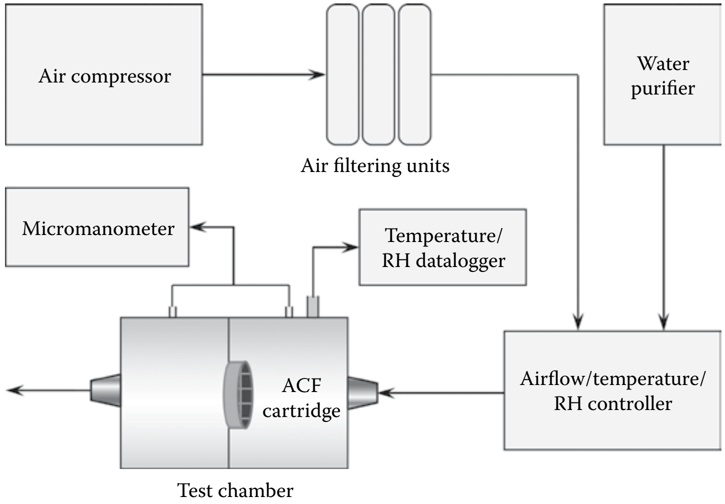

FIGURE 15.14
Experimental setup for pressure drop determination using constant airflow. (From Balanay, J.G. and C.T. Lungu. *Journal of Occupational and Environmental Hygiene*, 13 (2): 141–147, 2016, reprinted by permission of The American Industrial Hygiene Association, www.aiha.org and The American Conference of Governmental Industrial Hygienists, www.acgih.org.)

ACF materials. Figure 15.14 shows the schematic diagram of the experimental setup for the pressure drop determination.

15.4.1.4 Data Analysis

SPSS version 20 was used to analyze the data. The ANOVA test was used for the comparison of means. The pressure drop measurements across cartridges were compared among the different ACF cartridge configurations, between GAC and ACF cartridge configurations, and to the NIOSH requirements in breathing resistance testing for respirator cartridges. The mean adsorbent (ACF and GAC) weights were also compared by cartridge configuration. $P < 0.05$ was considered statistically significant.

15.4.2 Results and Discussion

15.4.2.1 Fiber Organization

The SEM images demonstrate the fiber organization of the ACF materials. At 50× magnification, the AC illustrated tightly woven fibers that show a denser appearance, while the AF types had more randomly distributed, nonwoven loose fibers that give a spongier appearance (Figure 15.15). At higher magnifications (200× and 800×), the AC showed fibers more tightly bundled together, while the fibers of AF1 were separated from each other, showing more spaces between them (Figure 15.16).

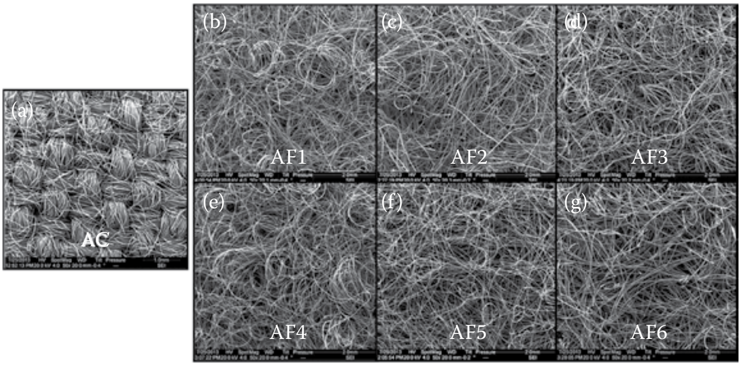

FIGURE 15.15
SEM images of activated carbon fibers at 50× magnification: (a) ACF cloth (AC) and (b–g) ACF felt (AF). (From Balanay, J.G. and C.T. Lungu: *Journal of Occupational and Environmental Hygiene,* 13 (2): 141–147, 2016, reprinted by permission of The American Industrial Hygiene Association, www.aiha.org and The American Conference of Governmental Industrial Hygienists, www.acgih.org.)

15.4.2.2 Pressure Drop

15.4.2.2.1 Single-ACF Type Cartridges

The 20-minute average pressure drop measurements across respirator cartridges were obtained for each test. Table 15.6 shows the average pressure drop and weight measurements across nine single-ACF type cartridge

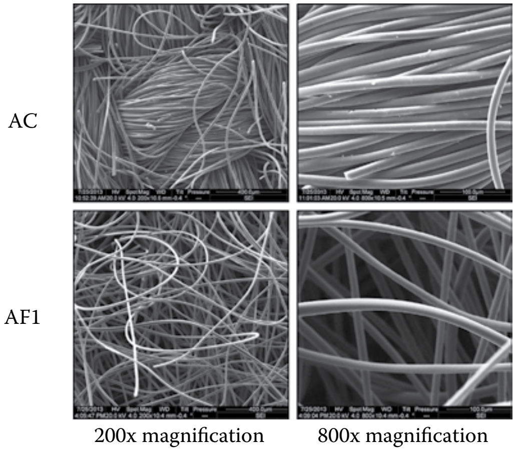

FIGURE 15.16
SEM images of activated carbon fibers at 200× and 800× magnifications. (From Balanay, J.G. and C.T. Lungu. *Journal of Occupational and Environmental Hygiene*, 13 (2): 141–147, 2016, reprinted by permission of The American Industrial Hygiene Association, www.aiha.org and The American Conference of Governmental Industrial Hygienists, www.acgih.org.)

configurations and a GAC cartridge. The average pressure drop results for cartridges filled with GAC (23.13 ± 1.14 mmH_2O) and all AF types (CS1–CS8, ranging from 23.71 to 39.93 mmH_2O) were within the NIOSH inhalation resistance requirement of 40 mmH_2O. However, the cartridge filled with AC (CS9) had a mean pressure drop (85.47 ± 3.67 mmH_2O), which exceeded twice the NIOSH limit and was significantly higher than the mean pressure drop of the AF ($p < 0.01$) and GAC cartridges ($p < 0.01$). This may be attributed to the tighter weaving of the fibers of AC as shown in the SEM images (Figures 15.15 and 15.16), thus resulting in the restriction of airflow through the material. The high pressure drop across the AC cartridge demonstrated that the use of 100% AC in cartridges is not recommended and will likely result in respirators that are difficult to breathe through. Compared to the GAC cartridge, all the AF cartridges (CS1–CS8) in general had a significantly higher mean pressure drop (32.77 ± 5.44 mmH_2O, $p = 0.01$) but had significantly much lower mean adsorbent weight (4.74 ± 1.66 g, $p < 0.01$) compared to the GAC (60.34 ± 0.10 g) (Table 15.6). This demonstrated the AF weights in cartridges that were 15.2% of the GAC weight or less, and thus showing potential for lighter respirator cartridges. CS1, CS2, and CS3 cartridges contain the same ACF type but with increasing density, resulting in increasing pressure drop (Table 15.6). Cartridges filled with different AFs showed varied pressure drop measurements depending on the density of the adsorbent materials, wherein less dense AF types had lower pressure drop. Among the AF types, the CS8 cartridge (filled with AF6) has the highest mean pressure drop (39.93 ± 0.67 mmH_2O), which was essentially at the NIOSH limit and was significantly higher than the mean pressure drop of the other AF cartridges, CS1–CS7 ($p < 0.01$ to $p = 0.04$). This may be due to the AF6 having the most dense material (0.07 g/cm^3) among the AF types, although its fibers were nonwoven.

15.4.2.2.2 Combination-ACF Type Cartridges

The ACF combinations placed in a cartridge were designed to have a pressure drop below 40 mmH_2O. The ACF types and number of layers in the ACF combination were determined based on preliminary pressure drop measurements across each ACF type at a different number of layers. Table 15.7 shows the average pressure drop and weight measurements across the 15 combination-ACF type cartridge configurations (ranging from 27.39 to 32.81 mmH_2O) and a GAC cartridge (23.13 ± 1.14 mmH_2O). Compared to the GAC cartridge, each of the ACF cartridge configurations (CC1 to CC15) had a significantly higher mean pressure drop ($p < 0.01$ to $p = 0.05$) but had significantly lower mean adsorbent weights (ranging from 4.79 to 6.78 g; $p < 0.01$) compared to the GAC (60.34 ± 0.10 g) (Table 15.7). This demonstrated that ACF in cartridges were 11.2% of the GAC weight or less, resulting in lighter respirator cartridges.

One specific purpose of combining ACF types in a respirator cartridge is to decrease the pressure drop to acceptable values when using the more dense ACF materials (i.e., AC, AF6) by incorporating less dense materials with them. Considering that adsorption capacity is related to the adsorbent mass, which consequently is related to its bulk density, it is expected that the more dense ACFs have higher adsorption capacities for airborne pollutants, which is essential in respiratory protection application. In the ACF Study Phase 1, AC was shown to have higher adsorption capacities and longer breakthrough time for toluene compared to AF, which may be attributed to the AC's denser form and smaller micropore diameter. Thus, in CC1 and CC2 cartridge configurations, AC was combined with AF1, which was the thinnest AF (0.23 cm) and among those with the lowest density (0.043 g/cm^3). Compared to the CS9 cartridge (100% AC) with an unacceptable pressure drop (85.47 ± 3.67 mmH_2O), such combinations (predominantly composed of AF) reduced the pressure drop to acceptable values (32.81 ± 1.53 and 27.56 ± 2.42 mmH_2O for CC1 and CC2, respectively). Moreover, in CC3 and CC4 cartridges, AF6, which was the thickest (0.50 cm) and most dense (0.070 g/cm^3) among the AF types, was combined with AF1. Compared to the CS8 configuration (100% AF6) with a pressure drop almost at the NIOSH limit (39.93 ± 0.67 mmH_2O), such AF combinations resulted in much lower pressure drop values (28.91 ± 0.14 and 31.06 ± 0.43 mmH_2O). This demonstrates the possibility of achieving acceptable pressure drop by combining dense ACF types with high pressure drop with other less-dense ACF types with low pressure drop, with the goal of obtaining a compromise between absorbent bulk density and permeability.

15.5 Summary and Conclusion

Based on the breakthrough characteristics of toluene, particularly the breakthrough and saturation times, ACF may provide sufficient respiratory protection in environments with lower toluene concentrations (i.e., 50 ppm) for extended periods. Comparing the ACF forms (AC vs. AF), AC provided longer protection against toluene than AF at equivalent bed depth based on its longer breakthrough time. This is likely attributable to the denser form of AC compared to the nonwoven form of the AF, and therefore greater mass of adsorbent carbon present. Moreover, at a given toluene concentration, the 10% breakthrough time generally increased as the ACF specific surface area increased. This is explained by the increasing microporosity of each ACF form as the specific surface area increases.

The ACF with the lowest surface area, regardless of form, had the highest critical bed depth due to the least amount of available adsorption sites per ACF bed depth. The AC had a significantly lower critical bed depth than the AF with similar surface area because of its denser and thinner form.

Moreover, the adsorption capacity increased as the surface area increases for both forms of ACF due to the increasing amount of available adsorption sites per ACF mass. The AC had a significantly higher adsorption capacity than the AF with similar surface area due to their difference in micropore size distribution, wherein the AC had micropores of smaller diameter. ACF in respirators may be more appropriate for longer term use in environments with lower toluene concentrations, and may be used as short-term respiratory protection in performing quick tasks or during emergency escape for higher toluene concentrations. Based on adsorption characteristics, ACF, particularly AC with the highest specific surface area, has a good potential for application in the development of thinner, lighter, and more efficient respirators.

Upon investigating further the ACF composition that may result in respirator cartridges with acceptable breathing resistance, all studied realistic cartridges with single AF types showed acceptable pressure drop based on NIOSH certification requirements, as well as cartridges with certain combinations of AC and AF types. All ACF cartridges, either single- or combination-ACF type, were shown to have much less weight than GAC cartridges, thus indicating potential for the development of lighter respirators. Although shown to have higher adsorption capacity in Study Phase 1, AC was found to have unacceptably high pressure drop and are, therefore, not recommended for use in respirators if used by itself (i.e., 100% ACF) at the cartridge thickness or bed depth (i.e., 1 inch) tested in this study. AF by itself may be more appropriate as adsorbent materials in ACF respirator cartridges in terms of acceptable breathing resistance. However, AC may still be utilized in respirator cartridges if used in fewer layers in combination with AF types with lower pressure drop. Such combination techniques may also be used for denser AF types to further reduce pressure drop across the cartridge. Another option to reduce pressure drop while using 100% of these dense ACF materials would be reducing the bed depth of the cartridge (e.g., 1/2 inch).

The potential of ACF for use in realistic cartridges for respiratory protection was assessed in Study Phase 2 based on pressure drop alone. However, the adsorption characteristics (i.e., adsorption capacity, breakthrough) of these tested ACF cartridge configurations with acceptable breathing resistance must be further investigated to determine their service lives for protection against toluene at different concentrations, as well as against other VOCs and gases (e.g., sulfur dioxide and chlorine). The effect of various environmental conditions (i.e., temperature, relative humidity) and worker scenarios (i.e., sinusoidal vs. constant airflows, breathing rate) on the ACF cartridge's adsorption characteristics may also be investigated. Considering that the adsorbent mass in these ACF cartridge configurations is lighter compared to a typical GAC cartridge and that adsorbent mass is related to adsorbate captured, it is important to understand the effects of each configuration to these adsorption characteristics in the next study phase. Other factors that may be studied further is the possibility of encasing the ACF adsorbent in lighter materials (i.e., to produce an air-purifying media similar to a pancake filter for particulates) and of developing lighter and thinner N95-like ACF respirators. The next phase of the ACF study will be beneficial in gaining better knowledge of the appropriate use of ACF in respiratory protection, which can be translated into the development of the optimum configurations of ACF respirators for the improvement of user comfort, compliance and, eventually, worker protection against airborne pollutants.

Acknowledgments

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Funding Sources

These studies were supported by funding from the National Institute for Occupational Safety and Health (NIOSH), R01 Grant # OH 008080 and Grant # 2T42OH008436. Its contents are solely the responsibility of the author and do not necessarily represent the official views of NIOSH.

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Section V

Respiratory Protection for Health Care and Infectious Disease

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16

Facemasks and Respirators for the Prevention of Infection in Healthcare and Community Settings

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16.1 Introduction

16.1.1 Infection Control and Personal Protective Equipment

Emerging and reemerging infectious diseases are a continuing threat globally. Various pharmaceutical and non-pharmaceutical infection control measures are employed in healthcare and community settings to control infectious diseases. Most research has focused on pharmaceutical measures such as drugs and vaccines, but personal protective equipment (PPE) and other non-pharmaceutical measures are often the first available protection for frontline responders. These infection control measures are generally categorized according to three levels of hierarchy: administrative control measures, environmental control measures, and use of PPE (Siegel et al. 2007, WHO 2014a). Administrative control measures include elimination of risk, substitution, and engineering controls. These controls require development of policies and procedures, assigning responsibilities, risk assessment, source control, education, and training. Environmental control includes measures aimed at reducing the spread of infections through room design, isolation and air exchange measures such as proper ventilation, establishing airborne infection isolation rooms and systems for cleaning and waste disposal. PPE includes clothing or equipment used to protect from biological, chemical, and other hazardous substances such as gloves, gowns, aprons, goggles, face shields, surgical caps, facemasks, and respirators. PPE is considered the last line of defense in the infection control hierarchy and is recommended in combination with other control measures. However, in the event of an outbreak or a pandemic, the nature of the pathogen may be unknown and drugs and vaccines may not be available in the early phase, making PPE critical (Bell et al. 2006).

PPE should also be seen from two perspectives: as an infection control strategy to protect patients and as an occupational health and safety strategy to protect the health of healthcare workers (HCWs). PPE guidelines and protocols in healthcare, however, have developed largely around infection control and have focused on patient safety, with less attention to healthcare worker safety (MacIntyre et al. 2014a,b,c). PPE is required for first responders (including paramedics, border control staff, and emergency services), hospital workers, as well as staff in primary care, public health, or involved in biological waste disposal.

The choice of infection control measures generally depends on the nature of the infectious agent, routes of transmission, severity of disease, number of cases (sporadic, outbreak, or pandemics), geographical spread, and availability of prevention and control measures (MacIntyre et al. 2014c). The precautionary principle is recommended when there is uncertainty about any of these parameters, and especially if the consequences of infection are severe (MacIntyre et al. 2014a,b,c). A multi-faceted approach using a combination of the various infection control strategies is generally recommended to decrease the transmission of infectious diseases. Infection control strategies also need to be tailored for the setting and would be different in a high-risk setting, such as intensive care, compared to a general ward or community clinic in healthcare and community settings. HCWs are on the frontline when it comes to dealing with infectious disease and are at increased occupational risk of contracting infections compared to the general public. Common infection control strategies used in healthcare settings are triage, isolation of infective cases, negative pressure rooms, cohorting, use of drugs, vaccines, and PPE. During large outbreaks and pandemics, the focus may shift to mitigation, delaying spread, and reducing community transmission through population-based measures. Common interventions used to reduce the spread of epidemics in the community are quarantine, social distancing, and use of PPE (Bell et al. 2006).

16.1.2 Types of PPE

Various types of PPE are used in healthcare and community settings to protect from respiratory and other infections. PPE can be categorized into:

- Respiratory protection (facemasks and respirators)
- Skin protection (full body suit or gown/apron, surgical hood/cap, gloves and shoes/shoe cover)
- Eye protection (goggles or face shield)

16.1.2.1 Respiratory Protection

As respiratory infections are mostly transmitted through the inhalation route, appropriate respiratory protection is required (IOM 2006, OSHA 2014). Based on aerobiology experiments from the 1940s which suggested that large respiratory droplets settle quickly close to the source of emission, and small droplets remain airborne at a greater distance (Wells 1943, 1946, Wells et al. 1948, Brosseau and Jones 2014), respiratory transmission of infection is usually dichotomized into droplet or airborne, and infection control policies are formulated around this dichotomy. Yet scientific research shows that the scientific basis of this assumption is incorrect, and that both small and large droplets can be present close to the source. Infection transmission is more complex than simply being airborne or droplet. Facemasks (also known as "surgical" or "medical" masks) and respirators are the most common PPE used to protect from respiratory transmission. Facemasks are mostly used to avoid contact with splashes and sprays of body fluids or blood and to prevent the spread of infections from sick patients (Siegel et al. 2007). They are not designed for respiratory protection and are not classified as respiratory protective devices (IOM 2010). Respirators (which may be disposable or reusable) are designed for respiratory protection and are widely accepted in healthcare settings to protect HCWs from acquiring respiratory infections (MacIntyre et al. 2011, 2013, WHO 2014a). Respirator use requires implementation of comprehensive respiratory protection programs, including regulation, certification, training, fit testing, medical evaluation, surveillance, storage, inspection, and decontamination.

16.1.2.2 Skin Protection

Gloves are used to protect the hands from infections which transmit through direct contact. The transmission may occur directly through non-intact skin or contamination through touching of the hand to a mucosal surface. Hand washing is strongly recommended before and after use of gloves. Hands can be washed with soap and water, antiseptic solutions, and antibacterial microfiber towel. Alcohol-based hand rubs (ABHRs) may not be effective in reducing *Bacillus atrophaeus* (a surrogate of *Bacillus anthracis*) spores, and proper hand wash is recommended using soap and water and other antiseptic liquids (Weber et al. 2003). For some infections, such as Ebola, double gloving is also recommended to increase the safety of removal (McLaws et al. 2016).

Disposable or washable gowns are used to avoid soiling of the clothes with blood and body secretions. Gowns prevent contamination of clothes which may otherwise lead to transferring microorganisms from one area to another. Disposable or washable gowns are used to avoid soiling of clothes with blood and body secretions. Gowns are not recommended as a measure to prevent respiratory pathogen transmission (such as influenza) in general, except during certain procedures such as intubation and resuscitation (US Department of Health and Human Services 2005). However, gowns are recommended if the outbreak is also associated with bleeding or diarrhea (US Department of Health and Human Services 2005) and in the case where a new emerging infection is suspected, for example, severe acute respiratory syndrome (SARS) (WHO 2014b).

16.1.2.3 Eye Protection

Goggles or face shields are used to protect the transmission of biological agents directly into the eyes or self-contamination from contaminated hands. Studies show that trans-ocular transmission of influenza and other viruses may occur, and transmission may be reduced further if eye protection is used with respiratory protection (Bischoff et al. 2011). Conjunctivitis associated with H7N7 avian influenza infection reported in the Netherlands also suggests that transmission may occur through the conjunctiva (Du Ry van Beest Holle et al. 2005). However, goggles or face shields are not routinely used for all diseases that transmit through direct contact. In healthcare settings, they are mainly recommended to avoid sprays or splashes of infective material (US Department of Health and Human Services 2005) and also while dealing with serious pathogens. For example eye protection was strongly recommended for the prevention of transmission of SARS (WHO 2014b) and Ebola (McLaws et al. 2016).

16.2 Facemasks and Respirators

Protection from masks is a function of four theoretical factors:

1. Physical barrier: this simply blocks skin contact with splashes or sprays, and depends on the surface area and permeability of the material.
2. Filtration: this is a function of the fabric or material chosen, and its ability to filter airborne particles.

3. Fit around the face: this is a function of the design of the mask, and the ability to prevent air leaking through the sides of the mask.
4. Antimicrobial properties of the material. However, commercial products with the feature are not widely available.

The use of facemasks by surgeons in operation theaters (OTs) to protect the wound from contamination was first documented in the late nineteenth century (Belkin 1997, Weaver 1919). In the early twentieth century, cloth masks were used to protect from diphtheria, scarlet fever, and other respiratory infections (Capps 1918, Weaver 1918, 1919). HCWs and the general public also used cloth masks during the Spanish influenza pandemic (1918) (NSWDPH 2007), Brooks 1918, Whitelaw 1919, Kellogg and MacMillan 1920), Manchurian epidemic (1920–1921) (Wu 1926), and plague epidemic (1924) (Viseltear 1974). Cloth masks were also used by HCWs to protect from TB during the 1930s and 1940s (Wheeler 1938, Lurie and Abramson 1949, McNett 1949). During this period, facemasks had been also used by sick patients to prevent the spread of infection to others, also termed "source control" (Weaver 1919, Rockwood and O'Donoghue 1960, Jensen et al. 2005). Medical masks were developed in the midst of twentieth century (Kiser and Hitchcock 1958, Madsen and Madsen 1967) and since then largely replaced use of cloth masks except in low resource settings, where they are still widespread in use. Respirators are relative new products and their use is increasing rapidly particularly in high resource settings (OSHA 2016a).

16.2.1 Types of Facemask and Respirators

The following types of facemasks and respirators are commonly used in healthcare, community, and industrial settings (IOM 2006, OSHA 2014):

1. Facemasks
   a. Medical or surgical masks (here after "medical masks")
   b. Cloth, cotton, or gauze masks, (here after "cloth masks")
2. Respirators
   a. Air purifying or particulate respirators
      i. Disposable filtering facepiece respirators (FFRs)
      ii. Reusable or elastomeric respirators
      iii. Powered air-purifying respirators (PAPRs)
   b. Air supplying or atmosphere-supplying respirators
      i. Supplied-air respirator (SAR)
      ii. Self-contained breathing apparatus (SCBA)

Air supplying or atmosphere-supplying respirators are generally not used in healthcare, and are reserved for chemical, smoke, or gas contamination, so will not be reviewed further. Characteristics of various types of facemasks and respirators used in healthcare are presented in Table 16.1.

16.2.2 Facemasks (Medical and Cloth Masks)

16.2.2.1 Shape

Medical masks are generally available in two shapes: flat-pleated or duck-billed and premolded. Most medical masks are not able to be fitted to the face, and there is significant air leakage between the mask and the face. Flat-peaked or duck-billed-shaped medical masks are attached to the head with two ties. Premolded medical masks are attached to the head with a single elastic string (MacIntyre et al. 2011, 2014c). Some medical masks are adjusted to the bridge of the nose with a flexible metal piece. Cloth mask are generally flat-pleated and attached to the head with a single elastic string or two ties.

16.2.2.2 Material and Filtration Mechanism

Medical masks are made of a three ply structure of nonwoven material, usually polypropylene (IOM 2006, US FDA 2014), spun-bonded, melt-blown, or wet-laid (US FDA 2014). Cloth masks are made of one or two layers of cotton, gauze, or silk (Chughtai et al. 2013a). Cloth masks are mostly used in resource-limited settings (IOM 2006). Filtration of facemasks through the mask material is by mechanical impaction, however a significant amount of air can leak between the mask and face as well. The risk of infection has been shown to be higher in wearers of cloth masks, possibly because of moisture retention and low frequency of cleaning (MacIntyre et al. 2015).

16.2.2.3 Regulation

In the United States, the FDA oversees the process of premarket notification submissions of medical masks and reviews the testing data provided by manufacturers (so-called "510(k)" submissions) to approve for marketing. Mask manufacturing companies are required to provide a description of the product, including material used, specification and dimensions, style and design features (US FDA 2014). The European standard for the regulation of medical masks (EN 14683:2005) requires manufacturers to perform testing and "self-certify" the device for EC approval under the Medical Devices Directive (93/42/EEC) (3M 2014a). In Australia, medical masks are required to meet Australia Standard AS 4381 (Standards Australia Limited/Standards New Zealand 2002). In most developing countries, regulations do not require use of medical masks, and the use of cloth masks is not regulated in any part of the world (Chughtai et al. 2015a,b,c).

TABLE 16.1

Characteristics of Various Types of Facemasks and Respirators Used in Healthcare

	Medical Masks	Cloth Masks	Filtering Piece Respirators (e.g., N95)	Elastomeric Respirators	Powered Air-Purifying Respirators
Sizes	Usually one size	No standard size	Range of sizes in some models	Facepiece in three sizes: small, medium, and large	Facepiece in three sizes: small, medium and large
Disposable or reusable	Disposable	Disposable	Disposable	Reusable	Reusable
Intention to use	Source control by patient or HCW in OT Prevent from splashes of blood and body fluids	Source control by patient or HCW in OT Prevent from splashes of blood and body fluids	Respiratory protection	Respiratory protection	Respiratory protection, in high-risk situations
Type of filters/ cartridge used	No	No	Particulate (N, P, or R types)	Particulate (N, P, or R types), gas/vapor (organic vapor, acid gases, ammonia/methylamine, formaldehyde, multi-gas) or combination particulate and gas	Particulate, gas and vapor cartridges
Filtration mechanism	Mechanical impaction	Mechanical impaction	Impaction, interception, diffusion and electrostatic attraction	Impaction, interception, diffusion and electrostatic attraction	Impaction, interception, diffusion and electrostatic attraction

(*Continued*)

TABLE 16.1 (*Continued*)

Characteristics of Various Types of Facemasks and Respirators Used in Healthcare

	Medical Masks	**Cloth Masks**	**Filtering Piece Respirators (e.g., N95)**	**Elastomeric Respirators**	**Powered Air-Purifying Respirators**
Filtration capacity	Protect from large particles, that is, >100 microns	No data	Protect from small particles, that is, <100 microns	Protect from small particles, that is, <100 microns	Protect from small particles, that is, <100 microns
Facial fit	No	No	Yes	Yes	Yes
Fit testing	Not required	Not required	Required	Required	Required
Fit (user seal) check	Not required	Not required	Required	Required	Required
Trainings required to use	No	No	Yes	Yes	Yes
Regulations and certification	No	No	Yes	Yes	Yes
Test protocols	Particle filtration efficacy, bacterial filtration efficacy, fluid resistance, and flammability testing	No	Filtration efficacy Total inward leakage	Filtration efficacy Total inward leakage	Filtration efficacy Total inward leakage
Extended use	No data available	No data available	No data available	No data available	Yes, depending on battery
Reuse after decontamination	Not recommended	Can be used after washing with but not data available	Not recommended	Yes, according to manufacturer instructions	Yes, according to manufacturer instructions

(*Continued*)

TABLE 16.1 (*Continued*)

Characteristics of Various Types of Facemasks and Respirators Used in Healthcare

	Medical Masks	Cloth Masks	Filtering Piece Respirators (e.g., N95)	Elastomeric Respirators	Powered Air-Purifying Respirators
Protection against droplet infections	++	+	+++	+++	++++
Protection against airborne infections	–	–	+++	+++	++++
APF	No data	No data	10	Half mask—10 Full mask—50	1000
Easy to don/doff	+++++	+++++	++++	+++	++
Comfort with prolong use	+++	+++	++	++	+++++
Used with facial hair	Yes, as facial fit is not required	Yes, as facial fit is not required	No	Yes, with full facepiece	Yes, with full facepiece
Weight	+	+	++	++++	+++++
Cost	+	+	++	++++	+++++
Availability	+++++	++++	+++	++	+

Sources: Powered Air-Purifying Respirator (PAPR) Concept Paper, CDC.
Occupational Safety & Health Administration (OSHA). Department of Labor.
This sign shows strength of variable, e.g. + low protection, ++++ high protection; + cost is low and +++++ cost is high

16.2.2.4 Efficacy and Use

Facemasks are used for two main purposes (Siegel et al. 2007, IOM 2010, WHO 2014a):

- Source control (worn by HCWs in operating theatre environment or by sick patients to prevent transmitting infection to others)
- Respiratory protection (worn by a well person to protect against acquisition of some infections)

16.2.2.4.1 Facemask Use as Source Control in Operating Theatre Environment

Facemasks were originally developed to prevent spread of infections from the wearer, that is, from both patients and HCWs, referred to as "source control" (Belkin 1997). The traditional use of facemasks was in OTs to reduce the transfer of potentially infectious body fluids from the surgeon to sterile areas, however the effectiveness of facemasks in preventing surgical site infections is yet to be proven. Many historical studies have showed that facemasks do not prevent surgical site infections (Orr 1982, Mitchell and Hunt 1991, Tunevall 1991). Lipp and Edwards (2014) conducted a systematic review and reported low efficacy of facemasks against surgical site infections. The rate of surgical site infections was even higher in the masked group than the control group in some of these studies (Orr 1982, Mitchell and Hunt 1991, Tunevall 1991). Laslett and Sabin (1989) evaluated the use of medical masks and surgical caps in 504 patients undergoing percutaneous cardiac catheterization. They concluded that medical masks and surgical caps were not necessary to prevent infections during cardiac catheterization. In a hospital-based study, facemasks were not used during approximately 1000 surgical operations, and there was no increase in the infection rate compared to the infection rate in the previous 5 years in the same hospital (Orr 1982). Tunevall conducted a large clinical trial in 1991 and examined the rates of post-operative infections in patients operated on by "masked" and "unmasked" surgical teams. The rate of surgical site infection was 3.5% (73/1537) in the no mask group compared to 4.7% (55/1551) in the mask group. The authors concluded that the use of facemasks may protect the surgical team from acquiring infections but does not prevent surgical site infections. Experimental studies have also demonstrated that small amounts of oral bacteria dispersed during normal breathing may not contaminate the operating field and the use of facemasks may not be necessary in the OT subject to the availability of proper ventilation (Mitchell and Hunt 1991).

In contrast to this, there are other studies which support the use of facemasks in OTs. Chamberlain and Houang (1984) started a randomized control trial in women having gynecological surgery. The trial had to be discontinued in the initial phase because the rate of wound infection was found to be higher without mask use. Alwitry et al. (2002) attempted to measure the amount of bacteria that fell on the operative field during cataract surgery by placing culture plates near the patients' heads. The amount of bacteria that fell on the operative field was significantly lower when the surgeon used a medical mask, compared to when the surgeon did not use a mask.

16.2.2.4.2 Facemask Use as Source Control by Sick Patients

Current evidence suggests that facemasks reduce the spread of infections from sick patients. Medical and cloth masks are commonly used to prevent spread of respiratory infections from the wearer (IOM 2010). In an experimental study, Johnson et al. (2009) reported that both medical masks and N95 respirators prevent the spread of the influenza virus from the wearer. Milton et al. (2013) collected samples of "fine" and "coarse" exhaled particles from 37 influenza cases before and after using medical masks. Wearing a medical mask was associated with 2.8-fold reduction in the shedding of "fine" viral aerosols and a 25-fold reduction in shedding of "coarse" viral aerosols (an overall 3.4-fold reduction, 95% CI 1.8–6.3). Dharmadhikari et al. (2012) checked the rate of infection in guinea pigs which breathed the air coming from the wards of multi drug resistant TB (MDR-TB) patients. The patients were grouped into "mask" and "no mask" groups and tuberculin skin test (TST) conversion rates were then observed among the guinea pigs. The rates of infection in guinea pigs when patients used and did not use masks were 40% and 76.6%, respectively, and the authors concluded that the risk of TB transmission might be reduced by 56% if patients used a mask.

Most clinical trials on facemasks have focused on the protection of the well wearer, rather than on source control (MacIntyre and Chugtai 2015). To date only two clinical trials has tested the use of medical masks worn for source control (on sick subjects to protect others from dissemination of infection from the source) in the community/household settings (Canini et al. 2010, MacIntyre et al. 2016). Canini et al. (2010) conducted a household trial to examine the role of facemasks as source control. The study could not find significant difference in two arms, however the trial was terminated early due to low recruitment and influenza A (H1N1)pdm2009 infection. Another study in China showed that medical masks may protect spread of respiratory infections from the wearer, however the study was small and underpowered to detect a significant difference in the intention to treat analysis (MacIntyre et al. 2016). There has been no clinical trial to examine the efficacy of masks as source control in a healthcare setting, yet mask use by sick patients is widely practiced globally. There is a need to conduct a large clinical trial in selected hospitals to examine the role of medical masks as source control.

The use of facemasks is particularly recommended by sick individuals in a hospital setting to prevent the spread of infection to other patients. HCWs may protect themselves through vaccination or use of PPE, but other patients may be vulnerable. Moreover, compliance with mask use may be higher in sick individuals compared to healthy HCWs. The use of facemasks by sick individuals is not only beneficial in healthcare settings, but may also help in reducing transmission in community settings, particularly to household members and other close contacts (MacIntyre and Chughtai 2015).

16.2.2.4.3 Facemasks Use for Respiratory Protection

Despite the fact that facemasks have been used for the prevention of respiratory infections for a long time, their role in respiratory protection is much debated. Cloth and medical masks had been used in the past to protect from various respiratory infections (Capps 1918, Weaver 1918, Whitelaw 1919, Armstrong 1920, Wu 1926, Eh 1949, Chughtai et al. 2013a). Currently medical masks are commonly used in the healthcare and community settings, and use of cloth masks is limited to low-resource countries where they are a cheaper, reusable option compared to disposable medical masks. Three clinical trials compared the efficacy of medical masks compared to respirators (Loeb et al. 2009, MacIntyre et al. 2011, 2013). There is some evidence that medical masks may also protect HCWs from droplet transmitted infections, clinical respiratory illness (CRI), and influenza-like illness (ILI), though they are less effective than a respirator (Chen et al. 1994, Seto et al. 2003, MacIntyre et al. 2011, 2013). Medical masks had been used to protect HCWs from SARS, and many studies showed that they were effective in reducing transmission of infection in healthcare settings (Seto et al. 2003, Loeb et al. 2004, Teleman et al. 2004). One potential benefit of medical masks could be protection from a severe form of disease due to less viral load. A study in Taiwan during the SARS outbreak showed low viral load in nasopharyngeal swabs of HCWs (24.36 ± 15.84 copies/mL) compared to non-HCWs (4346 ± 3246 copies/mL). The authors concluded that that facemask use might reduce viral load in HCWs, resulting in low morbidity and mortality, less secondary transmission, and few long-term complications (Lu et al. 2006).

There is a lack of sufficient data to support the effectiveness of cloth masks in blocking the transmission of infections (IOM 2006). To date only one clinical trial has been conducted to test the efficacy of cloth masks which showed that cloth masks are less effective compared to medical masks and may actually increase the risk of infection (MacIntyre et al. 2015). Laboratory studies have demonstrated that cloth masks may provide some protection, but much less than a respirator or a medical mask (van der Sande et al. 2008, Davies et al. 2013).

The role of facemasks in community settings is yet to be proven definitively, and most studies are inconclusive. Seven clinical trials have been conducted in community or household settings (MacIntyre and Chughtai 2015), and most of them failed to show the efficacy of facemasks in intention to treat analysis. However post-hoc analyses showed a protective benefit, given that interventions were applied early and participants adhered to facemask use.

16.2.3 Respirators

Respirators are defined as "respiratory filtering devices that provide protection against inhalation of small and large airborne particles" (CDC 2006a).

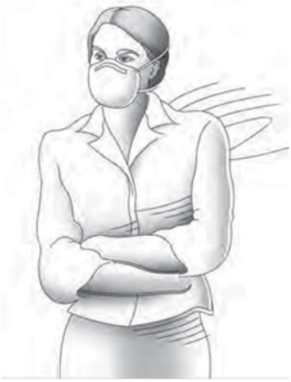
According to OHSA (2011), a "respirator is a device that protects from inhaling dangerous substances, such as chemicals and infectious particles." Respirators work through various mechanisms including filtering hazardous particles from the air, removing contaminants with chemicals, and supplying clean air from outside. Common types of respirators used in healthcare settings are air-purifying or particulate respirators and air-supplying or atmosphere-supplying respirators. Air-supplying respirators are used in very high-risk situations such as smoke exposure, chemical or gaseous exposures, where a separate air supply is required.

16.2.4 Air-Purifying Respirators

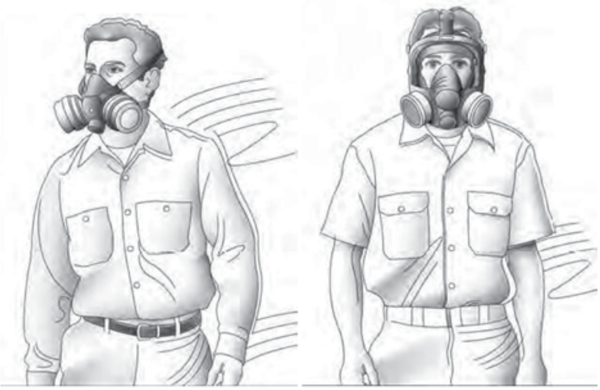
16.2.4.1 Types and Shape

Air-purifying respirators are further categorized into FFR or disposable respirators, elastomeric or reusable respirators, and PAPRs (Figure 16.1) (OSHA 2011). FFRs come in various shapes, for example, cup, duckbill, and molded. Reusable or elastomeric respirators are either full face or half face. Elastomeric respirators and PAPRs are reusable. Elastomeric respirators are either half or full masks.

PAPR is "a device equipped with a facepiece, hood or helmet, breathing tube, canister, cartridge, filter, canister with filter or cartridge with filter and a powered blower" (CDC 2008). It is of two types: tight fitting, with a seal to the face and neck (like a mask) and loose fitting (such as a hood), which may not completely seal the face and neck. PAPRs are also described as "respirators that protect the user by filtering out contaminants in the air and use a battery-operated blower to provide the user with clean air through a tight-fitting respirator, a loose-fitting hood, or a helmet" (IOM 2015). The components of a PAPR include a facepiece or hood/helmet, a breathing tube, a canister or cartridge with filter, a blower and a battery pack. Widely used negative pressure respirators (filtering facepiece and elastomeric) have significant disadvantages including high breathing resistance, acceleration of heat build-up, and CO_2 and moisture accumulation in the mask (OSHA 2008). This makes them difficult to tolerate over long periods of wear and can result in impaired professional performance, dizziness, and low compliance, which in turn increases the risk of noncompliance (Radonovich et al. 2009, MacIntyre et al. 2011, Kuklane et al. 2015). HCWs prefer respirators that are comfortable, keep them cool, and do not interfere with breathing (Baig et al. 2010). PAPRs are positive pressure devices because they use a blower to draw air through a filter into the facepiece. The airflow feels cool and refreshing. The protection of a PAPR is consistently higher than negative pressure respirators. Due to the positive airflow removing CO_2 and moisture, PAPRs are easier to wear over long periods of time. Despite these important advantages PAPRs are rarely used in healthcare.

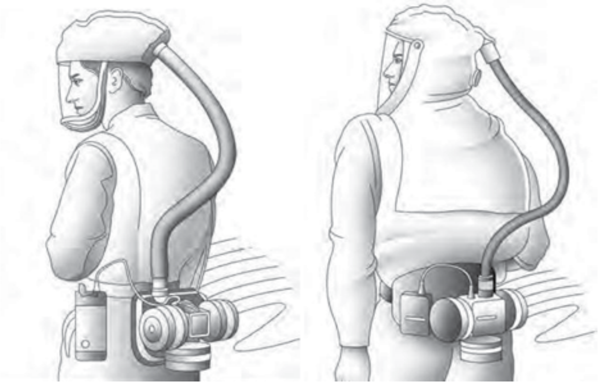


Filtering facepiece respirator



Half mask (elastomeric)

Full facepiece (elastomeric)



Loose-fitting powered air-purifying respirator (PAPR)

Hood powered air-purifying respirator (PAPR)

FIGURE 16.1
Respirator types. (Courtesy of Occupational Safety & Health Administration. U.S. Department of Labor Assigned Protection Factors for the Revised Respiratory Protection Standard. https://www.osha.gov/Publications/3352-APF-respirators.pdf.)

16.2.4.2 Material and Filtration Mechanism

FFRs are completely made of the filter material and are single use. The filters are typically made of polypropylene wool felt or fiberglass paper (NIOSH 1987, OSHA 2009b, 2011). The facepiece of elastomeric respirators is either of full face or half face, and made of rubber, neoprene, silicone, or plastic. Silicone is usually preferred because it is comfortable, flexible, and easy to wash. The facepiece of the elastomeric respirators may be cleaned and reused, however its cartridge is discarded and replaced.

FFRs and elastomeric respirators are non-powered. Instead, the wearer draws air in through the filter or cartridge, creating negative pressure inside the respirator. Some respirators also have an exhalation valve so that negative pressure is not created inside. Breathing is improved as valves are opened during the exhalation. However, respirators with exhalation valves should not be used when there is a chance of spreading an infection from the wearer (OSHA 2009b, 2011). PAPRs have a battery system, which is used to pull contaminated air through the filter piece. They use a high-efficiency particulate arrestance (HEPA) filter to protect the wearer against airborne infections and are used during aerosol-generating procedures (AGPs) such as intubation, suctioning, and bronchoscopy. Fit testing is not required for full-facepiece PAPRs and they can be used by men with facial hair, however half mask PAPRs need to be fit tested (OSHA 2009b, 2011). PAPRs are much more comfortable than FFRs and can generally be tolerated much longer. Battery time is generally long with warning indicators in case of low battery. However, PAPRs must be cleaned when used to protect against pathogens that can be spread by contact, and batteries need to be replaced. The required belt, hose, and battery pack may also become contaminated.

Three types of filters are used in cartridges of reusable respirators: particulate filters, gas/vapor filters, and combination filters (3M 2014b). Particulate filters are mostly used in healthcare settings and they only filter aerosols such as dust, mists, fumes, smoke, mold, and bacteria. Gas and vapor filters are mostly used in industrial settings and are different for organic vapor, acid gas, ammonia/methylamine, and formaldehyde. Combination filters protect from both particles and gases (3M 2014b).

The filtration process for particulate filters is different for large and small particles. Large particles do not pass through the filter media and collide with the respirator fiber and may be captured by interception, sedimentation, and inertial impaction. Small particles may pass the fiber filter through diffusion. As particle size decreases, the diffusive capacity of particles increases due to temperature. Electrostatic capture of the charged particles is another filtration mechanism, which facilitates interception and diffusion as well. Chemical decontamination is the method used by gas mask respirators (OSHA 2009b, 2011).

Air-purifying respirators are classified into three filter series (N, R, and P) depending on their ability to resist oil. The "N" means not resistant to oil, the

"R" means somewhat resistant to oil, and the "P" means strongly resistant to oil (i.e., oil proof) (OSHA 2011). Three filtration efficiency levels (i.e., 95%, 99%, and 99.97%) exist for N, R, and P series, thus making a total of nine different types. "N" series respirators are tested with sodium chloride aerosols, while "R" and "P" series are tested with oil based aerosols. The assigned protection factor (APF) is calculated by estimating the ratio of the number of particles outside the respirator to the number of particles inside the respirator (Table 16.2) (OSHA 2009b, 2011). Selection of the respirator depends on the nature of organisms, transmission mode, dissemination method, concentration of aerosols, and other environmental conditions (CDC, 2001).

16.2.4.3 Efficacy and Use

To date, only FFRs (N95) have been tested in the clinical setting. Among five clinical trials in healthcare settings, three compared the efficacy of masks with respirators. Two large clinical trials clearly showed the benefit of using respirators for CRI (MacIntyre et al. 2011, 2013). However, none of the studies showed the efficacy of respirators against laboratory-confirmed influenza, probably due to inadequate statistical power. Seven clinical trials have been conducted in community or household settings (MacIntyre and Chughtai 2015), and all except one (MacIntyre et al. 2009) examined the efficacy of only facemasks. Only one clinical trial in a household setting compared the

TABLE 16.2

Assigned Protection Factors for Commonly Used Respirators[a]

Type	Assigned Protection Factors	Remarks
Half-mask (FFR) (e.g., N95)	10	Needs to be fit tested
Half-mask (Elastomeric)	10	Needs to be fit tested
Full facepiece (Elastomeric)	50	Needs to be fit tested
Half-mask PAPR	50	Needs to be fit tested
Full-facepiece PAPR	1000	With Workplace Protection Factor[b]
Loose-fitting PAPR	25	No fit testing
Helmet/Hood PAPR	1000[a]	If Workplace Protection Factor[b] not performed then 25
Full facepiece SAR	1000	APF = 10,000 (if used in "escape" mode) Needs to be fit tested
Full Facepiece SCBA, Pressure demand or other positive-pressure mode	10,000	Needs to be fit tested

[a] Adapted from Occupational Safety & Health Administration (OSHA). Assigned Protection Factors for the Revised Respiratory Protection Standard. 2009a. https://www.osha.gov/Publications/3352-APF-respirators.pdf. (Accessed Nov 16, 2016)

[b] Study that estimates the protection provided by a respirator within a specific respirator program.

efficacy of medical masks and respirators and found rates of ILI were similar (MacIntyre et al. 2009).

Respirators are used to protect from inhaled droplet or aerosol particles, including infection, dust, smoke, gases, vapors, and sprays. Properly fitted respirators are designed to fit tightly to the face and have been found to provide better protection against airborne and droplet infections compared to medical masks (Checci et al. 2005, van der Sande et al. 2008, Gralton and McLaws 2010, MacIntyre et al. 2011, 2013). FFR are commonly recommended for airborne infections (e.g., TB) (Nicas 1995, Jensen et al. 2005, WHO 2009) and high-risk procedures (e.g., AGPs) in healthcare settings (Chughtai et al. 2013b, WHO 2014a). However, FFRs do not provide protection against vapor and gases. They also provide little protection against direct liquid splash/spray of blood and body fluids, and surgical N95 respirators are recommended for this.

Some studies have suggested that respirators should also be used to protect from exposure to "surgical smoke," which is an aerosol generated in surgery due to a laser or diathermy (Bruske-Hohlfeld et al. 2008, Ulmer 2008). The use of fit tested respirators is recommended in OTs to prevent inhalation of infective material from the surgical site which may include certain microorganisms and may be harmful to the surgical team (Benson et al. 2013). Researchers argue that the use of surgical masks may only prevent exposure to splashes of blood/body fluids during the operation, and OT staff should use a respirator to protect themselves from infective aerosols generated by modern surgical technologies (Benson et al. 2013).

FFRs are, however, difficult to wear for long periods of time due to increased heat, moisture, and CO_2 in the facepiece. FFRs with exhalation valves are significantly more comfortable, as the exhaled air is directed through a valve that also mitigates increases in temperature, relative humidity, and CO_2. There is some concern in healthcare settings that the exhalation valve may allow the release of infectious particles generated by the wearer, although there are no data to support or refute this (IOM 2006). Another type of respirator is the surgical respirator which offers the combined protective properties of both a FFR and facemask (OSHA 2008). They protect from respiratory infections as well as from splash and spray of blood and body fluids.

Elastomeric respirators and PAPRs are increasingly being used in the healthcare setting. Although there is no efficacy data to support their use, simulated studies have shown that they offer better protection compared to the disposable N95 respirator (Lawrence et al. 2006). The CDC also recommends the use of PAPRs when performing high-risk procedures on TB and Ebola patients (Jensen et al. 2005, CDC 2014c). PAPRs were also recommended and used during the SARS outbreak in Canada (Wong 2003). There are some important disadvantages of PAPRs, however. The blower can be noisy and annoying, interfere with communication, and requires batteries (generally a battery pack on the back, worn on a belt with a hose) that need regular charging (OSHA 2008). While some pieces can be disposable (e.g., hoods), most parts of a PAPR are not and require cleaning and disinfection between uses. Some of these parts (e.g., hoses, belts, and battery packs) are not easy to clean and disinfect; disposable covers may be required to prevent their contamination. PAPRs are more expensive to purchase and maintain, although the long-term costs can be less than disposable FFR if frequent use is required. When the blower and batteries are worn on a belt, they can interfere with healthcare tasks. Donning and doffing are more complex for a PAPR than a disposable FFR, but the chance of infection during doffing may be reduced because there is less chance for direct skin contact with contaminated hands or gloves (Zamora et al. 2006).

16.2.5 Policies and Practices on Use of Facemask and Respirators in Various Settings

There is an ongoing debate around the efficacy of various types of facemasks and respirators in healthcare settings. Many facemask studies have been observational (case control, cross sectional, or case studies) or conducted in controlled laboratory settings, and only recently has there been evidence from randomized clinical trials (RCTs) (MacIntyre and Chughtai 2015). Health organizations and countries have varying policies and practices on selection and use of facemasks and respirators in healthcare settings (Chughtai et al. 2013b, MacIntyre et al. 2014c).

Chughtai et al. (2013b) reviewed policies around the use of facemasks and respirators and examined guidance documents of the WHO, the CDC, and selected high, middle, and low-income countries. A lack of consistency in policies and guidelines was observed. Various types of facemasks and respirators were recommended for influenza (seasonal and pandemic strains), SARS, and TB. The WHO and the CDC have the same policy for seasonal influenza and TB, but different ones for pandemics influenza and SARS. Similarly selected counties have different policies on selection of facemask and respirators, which were in line with the WHO or CDC. MacIntyre et al. (2014c) examined the guideline on the use of facemasks and respirators for Ebola virus disease (EVD) during the 2014 outbreak. Although most countries and health organizations recommended a respirator to protect from EVD, some recommended medical masks as well. Another inconsistency was varying recommendation for frontline HCWs and laboratory workers, with a lower level of protection recommended for frontline HCWs compared to lab workers for Ebola. Of all the guidelines of selected countries and health organizations, only two (UK and South Africa) have the same respiratory protection policy for HCWs and laboratory workers.

Due to conflicting polices and lack of clear guidance, HCWs have varying practices with the use of facemasks and respirators (Chughtai et al. 2015c). Some of these practices are not in line with national infection policy, are non-standardized, and are not evidence-based (Chughtai et al. 2015a,c). Current practices are also influenced by availability, resources, and risk perception.

During the Ebola epidemic of 2014, for example, the perception of risk and demand for respirators was high. Although the available evidence points to cloth masks increasing the risk of infection (MacIntyre et al. 2015), some health organizations recommend their use if respirators and medical masks are not available (IOM 2006). In a guidance document "Reusability of Facemasks during an Influenza Pandemic" by the Institute of Medicine (IOM) of the National Academy of Sciences, the members were hesitant to discourage the use of cloth masks despite acknowledging a lack of efficacy data at the time and the risk of infection to the wearer (IOM 2006). Similarly in a position paper, the Association for Professionals in Infection Control and Epidemiology (APIC 2009) in the United States also considered the use of cloth masks during pandemics in case of shortage of medical masks and respirators. In the infection control guidelines for "Viral Haemorrhagic Fevers in the African Health Care Setting," both the WHO and CDC recommended using cloth masks if respirators or medical masks were not available (CDC and WHO 1998). It has been augured that cloth masks may be the only option for low-resource countries which may have no access to respirators or medical masks. However, the increased risk of infection shown in our RCT of cloth masks (MacIntyre et al. 2015) suggests that improved low-cost options are required.

In Western countries, facemask and respirators are not commonly recommended or used in community and household settings (MacIntyre and Chughtai 2015), though they are used in many Asian countries. However, their use is recommended in industrial settings to protect employees from various hazards. In the United States, Occupational Safety & Health Administration (OSHA 2015) has developed its Respiratory Protection Standard to protect from occupationally acquired infectious and noninfectious hazards. Employers are required to evaluate respiratory hazards and are mandated to implement a respiratory protection program in the workplace.

16.2.6 Selection of Appropriate Respiratory Protection

Although medical masks are commonly used to protect from respiratory infections, they are not designed to provide respiratory protection. Medical masks have consistently lower filtration efficiency compared to respirators which varies according to the material used (Chen et al. 1994, van der Sande 2008, Gralton and McLaws 2010). Even multiple medical masks worn at the same time were found to be less protective than respirators (Derrick and Gomersall 2005). Even high-filtration efficacy masks will not be protective unless there is a good seal to the face, and masks are not built to have a good facial seal. Laboratory studies have also demonstrated that medical masks have a lower filter efficiency (ranging from 10% to 90%) (Oberg and Brosseau 2008) and a lower capacity to remove sub-micrometer-size bio-aerosols (Chen and Willeke 1992, Weber et al. 1993, Rengasamy et al. 2009a). In some guidance documents, medical masks are not even included in the list of PPE (IOM 2010).

Respirators are designed for respiratory protection, and properly fitted respirators provide better protection compared to a medical mask. Respirators have different APF (Table 16.2), which is defined by OSHA (2009a) as, "the workplace level of respiratory protection that a respirator or class of respirators is expected to provide to employees when the employer implements a continuing, effective respiratory protection program." The protection factor is measured by calculating the ratio of the concentration of airborne particles outside the respirator (C_o) to the concentration inside the respirator (C_i).

Commonly used medical masks and respirators provide an adequate physical barrier though full-face respirators provide superior protection. Medical masks have varied degrees of filtration, while respirators generally have three filtration efficiency levels (i.e., 95%, 99%, and 99.97%). Medical masks are not fitted to the face, but respirators are designed to be fitted around the face which is ensured by fit testing and fit checking. None of the currently used medical masks and respirators have antimicrobial properties, but this remains a potential design feature to improve protection.

The selection of respiratory protection depends on many factors which may be broadly categorized into characteristics of the infectious agent, host/individual, and organizational factors (Table 16.3). A risk analysis approach should be used to select facemasks/respirators in healthcare and community settings (MacIntyre et al. 2014c).

16.2.6.1 Nature of the Infectious Agent

The election of facemasks and respirators in healthcare settings mainly depends on the type of infection and transmission mode (Table 16.4). Facemasks are generally recommended and used for infections believed to be transmitted by droplets, such as influenza and other common respiratory viruses. However, some organisms typically transmitted through droplet routes may also be transmitted through small particle aerosols. This mechanism is called opportunistic transmission (Roy and Milton 2004). For example, the primary modes of transmission of influenza are thought to be droplet and contact but it may also be transmitted through AGPs. Respiratory aerosols are generated during AGPs resulting in "aerosol transmission," which may be different from classical "airborne transmission" in that although the pathogen is inhaled in the same way as in airborne transmission, transmission may occur only over short distances (Brosseau and Jones 2014). However, infectious aerosol particles can travel short and long distance depending on particle size, humidity, and other environmental conditions (Wang et al. 2005, Tang et al. 2006). "Airborne transmission" occurs over long distances (e.g., TB), whereas, "aerosol transmission" is a phenomenon which can occur in diseases transmitted more often through other routes but which may also be transmitted by respiratory aerosols under certain circumstances, such as during AGPs. N95 respirators or higher are recommended for both airborne and aerosol transmission. A pooled analysis of two large RCTs shows that

TABLE 16.3

Facemask/Respirator Use for Selected Scenarios

	Healthcare Setting		**Community Setting**	
Disease	**Low Risk[a]**	**High Risk[b]**	**Low Risk[c]**	**High Risk[d]**
Seasonal influenza	1st choice: Medical mask[e,f] 2nd choice: Cloth masks[g]	1st choice: Respirator[e,f] 2nd choice: Medical mask[g] 3rd choice: Cloth masks[g]	Not recommended[e,f]	Not recommended[e,f]
Pandemic influenza	1st choice: Respirator[e] or medical masks[f], 2nd choice: Cloth masks[g]	1st choice[e,f]: Respirator, 2nd choice: Medical mask[g] 3rd choice: Cloth masks[g]	Not recommended[e,f]	1st choice: Medical mask[e,f] 2nd choice: Cloth masks[g]
MERS-CoV	1st choice: Respirator[f] or Medical mask[f]	1st choice: Respirator[e,f]	Not recommended	Not recommended
TB	1st choice: Respirator[e,f]	1st choice: Respirator[e,f]	Not recommended[e,f]	Not recommended[e,f]
Ebola virus	1st choice: Respirator[e] or Medical mask[f] 2nd choice: Cloth masks[g]	1st choice: Respirator[e,f], 2nd choice: Medical mask[g] 3rd choice: Cloth masks[g]	Not Recommended[f]	1st choice: Medical mask[f] 2nd choice: Cloth masks[g]

[a] Routine patient care, not within 1–2 meters of infective patient.

[b] High-risk situations, for example, AGPs, new or drug resistant organism, immunocompromised and other people with certain preexisting medical conditions.

[c] Home, non-crowded settings.

[d] Crowded settings, for example, public transport, preexisting illness, pregnancy, old age people (e.g., pandemic influenza), people touch human remains or in contact with infected animals (e.g., Ebola).

[e] Centres for Disease Control and Prevention (CDC).

[f] World Health Organization (WHO).

[g] Not stated explicitly: inference drawn from Institute of Medicine (IOM) guidelines and other policy documents prepared for low recourse settings (Cloth masks should be only used when no other options available).

N95 respirators provide superior protection for droplet transmitting infections as well (MacIntyre et al. 2013).

The separation of transmission into droplet versus airborne is however based on outdated studies. Most organisms can be transmitted through more than one mode, and the relative contribution of each mode is often difficult to quantify. In the event of a newly emerging pathogen, the transmission mode may be uncertain. Moreover, some infectious agents that transmit predominantly through droplet (e.g., SARS) or contact (e.g., Ebola virus) might require

TABLE 16.4

Primary Mode of Transmission for Respiratory Infections

Predominant Presumed Mode of Transmission	Examples of Virus	Examples of Bacteria
Droplet	Influenza A & B[a], Coronavirus[a]	*Streptococcus pneumonia*, *Haemophilus influenzae*
Airborne	Rhinovirus A and B	Tuberculosis, *Bordetella pertussis*[a]
Contact	Adenovirus, parainfluenza virus, respiratory syncytial virus, MERS-CoV[a]	

Source: MacIntyre CR, Chughtai AA. *British Medical Journal* (*Clinical Research ed*) 2015;350:1–12. Epub 2015/04/11

[a] Primary droplet but air borne transmission may occur in high risk.

superior respiratory protection due to other secondary modes of transmission. If there is high morbidity, mortality, or uncertainty about transmission mode, the precautionary principle should be followed. N95 or higher quality respirators should be the preference during outbreaks and pandemics where there is uncertainty around the transmission mode of the pathogen, especially when the disease in question has a high case-fatality rate and when there are no proven pharmaceutical interventions (IOM 2010, Chughtai et al. 2013b, CDC 2014a, WHO 2014a, MacIntyre et al. 2014c). All these factors should be considered when considering transmission-based precautions.

If the risk of transmission through the eye and other exposed body parts is high, a respirator equipped with a full facepiece, helmet, or hood should be used (Bollinger 2004). Finally, there is a complex relationship between bacteria and viruses in the respiratory tract, and dual infections appear to be common in HCWs, with multi-modal transmission (MacIntyre et al. 2014d).

For other contaminant, such as industrial particles, vapors, and gases, the selection of respirators with filters appropriate to the hazard is recommended. Chemical cartridges are recommended if risk of exposure to gases and vapors is high (Bollinger 2004). In contrast to healthcare setting, where respirators with "N" series filters are commonly used, respirators with "P" or "R" series filters may be used in industrial settings where oil particles are present in the atmosphere. Air-supplying respirators should be used in very high-risk situations, such as immediately dangerous to life or health (IDLH), oxygen deficit environments, and in the event of a bioterror attack.

16.2.6.2 Individual Factors

Individual factors are important in selection of respiratory protection, particularly for respirators. FFR and half facemask elastomeric respirators are not suitable for people with facial hair. Medical evaluation is necessary for FFR use as they may cause significant breathing problems. People with heart and respiratory diseases should not use FFR. Some people experience adverse events such as headache, skins reaction, and fatigue. Risk perception is also an important factor which may impact on compliance. A survey in the US revealed that HCWs were willing to work during a pandemic given their employer provided them respirators (Gershon et al. 2010).

16.2.6.3 Organizational Factors

Organizational factors are important because under Workplace Health and Safety (WHS) obligations, employers are responsible for providing a safe workplace for their employees. It is the responsibility of the employer to provide appropriate facemasks, respirators, and other PPE and adopt necessary administrative and environment control measures to minimize the exposure to hazardous substances at the workplace. At the organizational level, the permissible exposure limit (PEL) is calculated to estimate maximum use concentration (MUC). According to OSHA (2009a), "MUC means the maximum atmospheric concentration of a hazardous substance from which an employee can be expected to be protected when wearing a respirator, and is determined by the APF of the respirator or class of respirators and the exposure limit of the hazardous substance." Air sampling is done to estimate the exposure limit and select respirators with appropriate AFP.

Availability of facemasks and respirators of appropriate type and different sizes is of the utmost importance. Other organizational factors include resources for procurement, training, and fit testing, organizational culture, compliance with infection control practices, and monitoring and surveillance.

16.3 Respiratory Protection Program

A respiratory protection program is developed for healthcare organizations to ensure proper use of respirators. There are six main components of a respiratory protection program: (1) regulations and certification; (2) medical evaluation and surveillance; (3) training; (4) fit testing and fit checking; (5) availability, storage, and maintenance; and (6) reuse and decontamination.

16.3.1 Regulations and Certification

Respirator use should be regulated by an authority, and only certified respirators should be used by HCWs. In the United States, NIOSH regulates the testing and certification of respiratory protection equipment (NIOSH 1987). NIOSH tests filters for the effects of loading particle burden, temperature, and relative humidity, and requires a minimum filtration efficiency of 95%, 99%, or 100%. Filters can be certified for a range of efficiency classes (e.g., 95%, 99%, or

100%) as well as for their ability to withstand degradation as a result of loading or oil mist exposures. N95 filters cannot allow more than 5% of the challenge aerosol concentration to penetrate the filter, and would be expected to have less aerosol penetration with either larger or smaller particles than the size used in certification testing (IOM 2006, 2010). In Europe, European Norm (EN) standards are followed for testing respirators. Respirators need to be marked with "Conformité Européen (CE)," which means that the respirator meets the criteria of EN certification (European Directive 1989). Various types of the filtering facepiece respirators used in Europe are: FFR1, FFR2, and FFR3, which meet minimum filtration efficiencies of 80%, 94%, and 99%, respectively (Rengasamy et al. 2009b). FFR1, FFR2, and FFR3 are equivalent to NIOSH-certified N95, N99, and N100 respirators. In Australia, AS/NZS 1716 standard regulates respirator use, and P2 is equivalent to the N95 respirator (3M 2009). Regulation and certification is not routinely performed in low-resource countries and due to this, respirators of different filtration efficacy are used (Chughtai et al. 2015a,c). While regulations for filtration occur in many countries, the adequacy of facial fit is unregulated and therefore varies widely between respirators.

16.3.2 Medical Evaluation and Surveillance

Medical evaluation is an important component of a respiratory protection program to ensure that wearer can tolerate the respirator. Frontline responders should be medically fit and should not have serious cardiac or respiratory problems. Medical evaluation includes history of current and past illnesses, general physical examination, examination for facial scars, beards, body shape, and obesity (ECRI 2002). Moreover, medical surveillance program should be initiated to ensure proper use of respiratory protection and to record adverse events.

16.3.3 Training

Training, fit testing, and fit checking are important components of respirator use. The putting on (donning) and removal (doffing) of PPE is a laborious, slow process during which the smallest error can lead to contamination and infection (Kuklane et al. 2015). Training should be provided on the correct donning and doffing of respirators. Doffing is particularly a high-risk procedure, and the sequence becomes critically important if wearing full PPE gear (McLaws et al. 2016). During the doffing process, pathogens can be transferred from the contaminated surface of PPE to hands and other exposed body parts (Casanova et al. 2008). The outer layer of PPE should be decontaminated before starting the doffing process (MSF 2014, CDC 2014c).

Decontamination areas should be set up where staff don and doff the PPE. Decontamination sequences currently used for hazardous material emergencies should be used as appropriate for the level of protection employed. After removing PPE, frontline workers should have a shower using soap and water, and change into clean clothes (CDC 2001). For high-risk exposures, no item of clothing worn during patient care (including socks and underwear) should be taken home by the HCW.

16.3.4 Fit Testing and Fit Checking

Fit testing and fit checking are important as loosely or improperly fitted respirators do not provide adequate protection to the wearer. Respirators come in various sizes and designs to fit a range of face shapes and to prevent leakage around the respirator. Fit testing is important to ensure the efficacy of respirators and even certified respirators do not provide the optimal protection unless correctly fitted (Coffey et al. 1999, Lawrence et al. 2006). Fit checking or testing is not needed for PAPRs, and for this reason some hospitals prefer PAPRs.

Fit testing may be qualitative or quantitative. In the qualitative fit test, Bitrex™, saccharin, or irritant smoke is released into a chamber. If the wearer tastes or smells these agents, it indicates inadequate fit (OSHA 2016b). The qualitative test is used to check the leakage around the face, however it does not quantify the amount of leakage. Air sampling is performed from inside the respirator in quantitative testing and the amount of leakage is calculated though a fit testing instrument such as a Portacount (OSHA 2016b). Fit checking (or user seal check) is different from fit testing and is necessary to ensure that respirators fit the face and are properly sealed (Danyluk et al. 2011). Fit checking should be done every time a HCW dons an N95 respirator, and both positive and negative pressure should be checked. Negative pressure testing is done through covering the filtration surface of respirator with the hands and inhaling inward to create negative pressure. A properly fitted respirator will move slightly inward if correctly fitted, while in case of a leak, it will not. In a positive pressure check, the wearer exhales outward, and a bulge on the outer surface shows proper fitting.

Studies show that hospitals may not comply with fit testing requirements and HCWs generally do not comply with fit checking procedures. A California study undertaken during the influenza A (H1N1)pdm09 showed that HCWs performed a fit check after donning a respirator only in 20% (3/15) of observations (Beckman et al. 2013). A survey of the members of the Society for Healthcare Epidemiology of America (SHEA) showed that less than one third of hospitals fit tested their employees before the start of the influenza A (H1N1) pdm09 pandemic (Lautenbach et al. 2010). Lastly, another study showed that approximately one third of the HCWs infected with influenza A (H1N1)pdm09 in the United States were never fit tested (Wise et al. 2011). However, very limited data is available from low and middle income countries.

16.3.5 Availability, Storage, and Maintenance

Stockpiling of respirators and other PPE is important to provide equipment to all frontline staff and to maintain supplies. The CDC has stockpiled a large amount of medical supplies and PPE in case of emergency situations such as a terrorist attack, pandemic, or natural disaster (CDC 2015a). Supplies would be most needed in large metropolitan areas where most of the population lives. The CDC has developed a program, "Cities Readiness Initiative," to quickly distribute medical and other supplies to 72 major cities where more than 57% of the US population resides (CDC 2015b). This is an example of deployment prioritization for the medical stockpile.

16.3.6 Reuse and Decontamination

Decontamination of used respirators is necessary to avoid the spread of infection and risk of self-infection to the wearer. Currently, very few data are available about decontamination of various respirators. The National Academy of Sciences has proposed that decontamination methods must meet the following criteria (IOM 2006):

1. The method must remove the infectious threat
2. The method must be harmless to the user
3. The method must not compromise the integrity of the various elements of the PPE.

Decontamination of medical masks and disposable filtering piece respirators is usually not feasible because the materials of these products degrade with standard means of disinfection. Various decontamination methods have been studied to date, including autoclave, isopropyl alcohol, bleach, hydrogen peroxide, microwave, soap and water, ultraviolet radiation, and dry heat (IOM 2006). The reuse of N95 respirators has been studied by Viscusi et al. in various studies (Viscusi et al. 2007, 2009). In the first study (2007), they tested 10 chemical and nonchemical decontamination methods. Among those, hydrogen peroxide and UV germicidal irradiation (UVGI) caused the least changes in the filtration performance. In the second study (2009), they tested five methods for decontamination of N95 filtering facepiece respirators: UVGI, ethylene oxide, vaporized hydrogen peroxide, microwave oven irradiation, and bleach. UVGI, ethylene oxide, and vaporized hydrogen peroxide were proven to be more effective methods than others. None of the three methods caused much physical change in the respirators. However, the throughput capabilities of ethylene oxide and vaporized hydrogen peroxide were not confirmed. Similarly, Lore et al. (2012) tested UVGI, microwave-generated steam (MGS), and moist heat (MH) for decontamination of the FFRs and found these methods effective in reducing viral load.

Respirators with a separate filtering piece (elastomeric respirators) are reusable, however the facepiece needs to be cleaned and the cartridge replaced. Disposable or elastomeric respirators may be useful in the event of high demand during pandemics (IOM 2006, 2010). OSHA (2009b) recommends that NIOSH-certified elastomeric respirators can be used in situations when the reuse of respirators is required. OSHA has provided guidelines for cleaning and disinfection of respirators, which include disassembling (i.e., removing of filters, cartridges, or canisters), cleaning with warm water, and disinfection with detergent or disinfectant approved by the respirator manufacturer, rinsing and drying, and reassembling. Filters, cartridges, and canisters are replaced or repaired where necessary. Finally the respirator needs to be tested to ensure that all components work properly (OSHA 2014). The National Academy of Sciences has proposed that decontamination methods must meet the following criteria: (1) the method must remove the viral threat, (2) be harmless to the user, and (3) not compromise the integrity of the various elements of the respirator (IOM 2006). PAPRs should also be cleaned and disinfected after use. The instructions of the respirator manufacturer should be followed so that the agent used for the decontamination does not damage the respirator (Rengasamy et al. 2004).

Further research is required to test the effectiveness of various decontamination methods and to develop better materials which are resistant to degradation. Mask manufacturers generally recommend the single use of medical masks and filtering piece respirators and may not have a commercial interest in testing the reusability of masks and respirators due to financial and legal implications (IOM 2006).

16.4 Compliance

16.4.1 Compliance with Facemasks and Respirators

Regular and continuous use of facemasks and respirators is essential to provide maximum respiratory protection. Low compliance might result in acquiring infection regardless of how effective a respiratory protective device is. Compliance with the use of facemasks and respirators is reported to be low among HCWs and the general public and also dependent on various individual and environmental factors. Moreover, compliance decreases over the time due to overexertion and the presence of adverse events associated with mask use (Chughtai et al. 2016).

HCWs are reported to have low compliance with the use various PPE (Gershon et al. 1995, Evanoff et al. 1999). Wearing a facemask is considered "the most bothersome" (Nickell et al. 2004), and compliance with the use of facial protective devices is reported to be the lowest compared to other PPE (Madan et al. 2001, 2002, Chan et al. 2002). A systematic review suggests that compliance with the use of facemasks ranges from 4% to 55% (mean

30%) (Gammon et al. 2008). Self-reported compliance rates have been presented among clinical trials in HCWs. Compliance rates for cloth masks was reported to be 56% and for medical masks ranged from 66% to 84% (Jacobs et al. 2009, MacIntyre et al. 2011). Compliance with respirators varied according to the use and fit testing: 74% in fit-tested N95 respirators, 68% in nonfit-tested N95 respirators, 82% in targeted (in high-risk procedures only) N95 respirator use, and 57% in continuous N95 respirator use (MacIntyre et al. 2011, 2013).

Community and household studies also reported low compliance with facemasks and respirators among the general public. In some of these studies, both index (sick) cases and household members used a facemask, while in others, only household members used a facemask (MacIntyre and Chughtai 2015). Compliance with the use of facemasks was ranged from 45% to 52% in index cases and 21% to 68% in household members. Many individual and environmental factors also affect compliance with the use of facemasks and respirators (Chughtai et al. 2016).

16.4.2 Individual Factors

The use of facemasks is reported to be high in Asian cultures, such as in China and Japan (MacIntyre et al. 2011, 2013), but low in Western cultures (Ofner-Agostini et al. 2006, Seale et al. 2009). Among the individual factors, risk perception and the presence of adverse events are important predictors of compliance (Chughtai et al. 2016). Many studies show that adoption of certain behavior depends on the perceived risk. If the risk perception is higher, there is an increased probability of adopting protective behavior and vice versa. The Ebola outbreak in West Africa is an example when facemasks were recommended initially in the United States and recommendations were later changed following the infection of HCWs and concern about the high case fatality (MacIntyre et al. 2014b,c).

The presence of adverse events increases the risk of noncompliance with respiratory protection. Common adverse events associated with masks include general discomfort, pressure on nose, headache, breathing problems, and skin reaction (MacIntyre et al. 2011). In situations where high levels of PPE (full protective gowns and respirators) are required, such as for Ebola and other high-risk infections, duration of wear become important issues. During the 2014 Ebola epidemic, HCWs complained of unbearable heat, humidity, and discomfort when wearing PPE for periods longer than 30 minutes (Wolz 2014) resulting in HCWs removing PPE prematurely thus escalating disposable PPE costs and reducing HCW productivity and occupational risk.

A study testing the tolerance of respirators among US health workers found the discomfort increased with time if respirators were used continuously over prolonged periods of 8 hours (Shenal et al. 2012). However, most of these symptoms may be subjective, as no significant physiological effects (measured as changes to transcutaneous carbon dioxide and oxygen saturation) were observed with long-term respirator use among intensive care unit nurses in a study in the United States (Rebmann and Wagner 2009). Negative pressure respirators (e.g., FFRs) are difficult to tolerate for a long time and result in more discomfort, dehydration (especially in hot climates), impaired professional performance, and lower compliance, which in turn increases the risk of infection (Radonovich et al. 2009, MacIntyre et al. 2011, Kuklane et al. 2015). In addition, more layers of the currently used PPE make it impractical to care for patients and increase the risk of injury or self-contamination. HCWs prefer respirators that are comfortable, disposable, keep them cool, and do not interfere with breathing (Baig et al. 2010). For Ebola, for instance, given the serious shortage of HCWs in affected countries and high infection rates (Liese and Dussault 2004), PPE that enables HCWs to work more comfortably for longer time periods, without compromising safety, is an urgent research need.

16.4.3 Organizational Factors

Organizational factors include resources, availability of facemasks and respirators, supportive organizational culture, and availability of fit testing and monitoring (Shigayeva et al. 2007, Nichol et al. 2013). The main problem with the use of respirators is the direct cost of the products and the indirect cost of implementing comprehensive respiratory protection programs including training and fit testing. However, cost should not be a factor while selecting appropriate respiratory protection for HCWs, and best practice guidelines should be evidence-based. To maintain the functionality and capacity of the healthcare workforce during outbreaks or pandemics of emerging infections, HCWs need to be protected. Under the WHS obligations, employers are responsible to provide a safe workplace for their employees. There are very few cost-effective studies to compare the cost of medical masks and respirators and disposable versus reusable respirators.

The availability of PPE is also important to ensure use and is also a predictor of compliance (Nelsing et al. 1997, Gammon et al. 2008). Shortage of facemasks and respirators was observed in many countries during influenza (H1N1)pdm2009.

Supportive organizational culture is important as well. In some settings, mask use was mandated in hospitals for unvaccinated HCWs to improve influenza vaccine uptake (Caplan and Shah 2013, Stuart et al. 2014). There is also new evidence that in the healthcare setting, if most HCWs are compliant with the use of a respirator, they may protect other noncompliant users as well due to herd protection effects (Chen et al. 2016). This study also showed that at least 50% adherence with the use of N95 respirator is required to project from clinical respiratory infections.

16.5 Use of Facemask and Respirators in Special Situations

16.5.1 Facemask and Respirator Use in Outbreaks and Pandemics

Infectious diseases are a continuing threat with constant emergence or re-emergence of serious diseases in various parts of the world. Diseases originating from one region may spread rapidly to other regions due to human movement through travel, tourism, and trade, resulting in epidemics and pandemics. Epidemics of a new infectious disease may be devastating due to rapid global spread, high disease morbidity and mortality, and severe social and economic impacts. Rapid response is therefore required to control epidemics of emerging infectious diseases and to prevent morbidity and mortality. In the initial period of an outbreak, the characteristics of the pathogen may not be known, and a vaccine against the pathogen might not be available for many months or longer. Depending on the pathogen, drugs may or may not be available, and if available may not available for everyone. Therefore, non-pharmaceutical measures, such as isolation, quarantine, social distancing, and PPE, are required for frontline response in epidemic situations (Bell et al. 2006, WHO 2014a).

Although facemasks, respirators, and other PPE are generally considered as the last line of defense in the infection control hierarchy (IOM 2006), they may be the only available option in event of a large scale outbreak or pandemic. Facemasks and respirators were widely used in healthcare settings during SARS, influenza (H1N1)pdm, MERS coronavirus, and other outbreaks. Most studies showed their benefit in reducing transmission of infection and protection of HCWs (Seto et al. 2003, Loeb et al. 2004, Teleman et al. 2004). Economic studies show that the use of facemasks and respirators are cost-effective in high-risk settings particularly when transmission and mortality rates are higher (Lee et al. 2011, Mukerji et al. 2017). However, the efficacy of using facemasks in a community setting is yet to be proven, and most observational studies showed limited benefit of using facemasks in mass gathering situations (Barasheed et al. 2016).

16.5.1.1 Selection of Facemasks/Respirators for Outbreaks and Pandemics

Currently there are limited data on the efficacy of various types of facemasks and respirators during outbreaks and pandemics. All RCTs in healthcare and community settings measured CRI, ILI, and/or influenza, and the results may not be generalizable to other infectious diseases (MacIntyre and Chughtai 2015). Most clinical trials are conducted during normal influenza seasons, but the pathogenicity and transmissibility of a pandemic strain might be different. Two RCTs were conducted during the influenza A (H1N11)pdm2009, and both were terminated early (Loeb et al. 2009, Canini et al. 2010). In the first RCT, medical masks were being compared with the N95 respirators, and due to influenza A (H1N11)pdm2, all HCWs were asked to use N95 respirators (Loeb et al. 2009). In the second RCT, medical masks were being used as source control, and the trial was suspended due to the emerging pandemic (Canini et al. 2010). Due to conflicting evidence and strong cultural beliefs about infection control, health organizations and countries have different policies on the use of facemasks/respirators for pandemic influenza, SARS, MERS-CoV, and Ebola (MacIntyre et al. 2014c, MacIntyre and Chughtai 2015, Chughtai et al. 2015b).

Different strategies can used to select facemasks and respirators for an outbreak or pandemic. For example, OSHA recommends categorizing employees into very high, high, medium, or lower risk of occupational exposure in preparing for an influenza pandemic and stockpiling facemasks and respirators (OSHA 2008). In some cases, a reusable respirator may be selected to overcome the shortage of disposable respirators.

Medical masks may be used in the community setting if the risk of transmission is very high. Respirator use is generally not recommended, but one trial showed they may protect in the community (MacIntyre et al. 2009). However, supplies may not be available for everyone. As a last resort, homemade cotton/cloth masks may be used, although they have lower filtration efficacy and facial fit compared to the medical masks (Davies et al. 2013). In addition, research shows that cloth masks increase the risk of infection (MacIntyre et al. 2015).

16.5.1.2 Increased Use

The use of facemasks and respirators increases during outbreak and pandemic situations (Lee et al. 2011). The WHO estimates around 233 million outpatient visits, 5.2 million hospital admissions, and 7.4 million deaths will occur globally within a very short period in event of a new pandemic (WHO 2014c). The CDC (2006b) estimated that approximately 1.5 billion facemasks and 90 million respirators would be needed by the health sector and around 1.1 billion masks would be needed by the public for a 6 week pandemic influenza outbreak. A shortage of facemasks and respirators was observed in many countries during the influenza A (H1N1)pdm2009 outbreaks (Rebman and Wagner 2009, Beckman et al. 2013). The supply of respirators was exhausted in many US hospitals, and HCWs had to reuse their respirators or had to rely on other types of facemask (Rebman and Wagner 2009, Beckman et al. 2013).

16.5.1.3 Nonstandardized Use and Risk of Infection

Due to increased use during outbreaks and pandemics, many nonstandard practices may be observed such as extended use and reuse of facemasks and respirators. According to the CDC (2010), extended use refers to "the practice of wearing the same N95 respirator for repeated close contact encounters with several patients, without removing the respirator between patient encounters." The CDC (2010) also defines reuse as "the practice of using the same N95 respirator for multiple encounters with patients but removing it ('doffing') after each encounter." Currently data are lacking regarding the time period that the same mask or respirator may be continuously be used. Available data suggest that respirators may be used intermittently or continuously for around 8 hours (CDC 2014b), and adverse effects of facemasks increase with more than 8 hours of use (Shenal et al. 2012).

Disposable medical masks and respirators have a limited life span and can become deformed, damaged, saturated, or may become ineffective after a single use. In addition, constant use and moisture may lead to difficulty in breathing (IOM 2006). Single use of medical masks and FFRs is recommended, but this is not always feasible. During a pandemic or extended outbreak, medical masks and FFRs may not be available for everyone and reuse or extended use is needed in some situations. The reuse and extended use, however, may be associated with self-contamination given that the outer surface of medical masks or respirators may be soiled and could be a source of infection (Viscusi et al. 2009, IOM 2010). The number of viral particles and survival time are important factors to consider if reuse is deemed essential (IOM 2010). Research studies are required to test the safety and efficacy of reuse.

Health organizations and countries have developed some recommendations on the extended use and reuse of medical masks and respirators during outbreaks, pandemics, and other high demand situations (IOM 2006, OSHA 2009b, CDC 2010, CDC 2016). The CDC (2016) recommends extended use during SARS outbreaks provided the mask is not wet, soiled, or damaged. However, there are currently no clinical studies supporting this practice (Sonoma County Department of Health Services 2006, OSHA 2009b). Considering the high demand for respirators during pandemics, OSHA recommends the extended use of respirators if they are not soiled or damaged and are still functioning properly. Facemasks and respirators should be kept in a safe place, and the product should only be used by the same wearer (OSHA 2009b). During the SARS outbreaks, Health Canada (2003) advised medical masks and respirators could be reused if SARS was ruled out. In case of exposure to a confirmed SARS case, reuse of contaminated masks and respirators was discouraged. WHO advised HCWs to use respirators for an extended period for TB protection if the respirators are properly stored (WHO 1999). Extended use should be balanced against the risk of infection, and the wearer should not remove facemasks between patient encounters to avoid self-contamination (CDC 2010).

Another option is double masking, that is, using a facemask over a FFR to prevent soiling and to extend the life of a respirator (Roberge 2008). However, this may increase the breathing resistance (Sinkule et al. 2013). IOM (2006) has also recommended using facemasks over the respirators in a policy document on reusability of facemasks during an influenza pandemic. However, there is limited data on the effectiveness of this strategy, and more research is needed.

During the SARS outbreak the CDC recommended concurrent use of facemasks with respirators in case of low supplies (CDC 2016). In a policy document, the IOM (2006) recommended using a facemask over the FFR to extend its life and prevent contamination on the outer surface. Double facemasks were also used during SARS outbreaks in Taiwan (Chen et al. 2004), however there is no clinical data to show the effectiveness of this intervention. The filtration effectiveness of multiple medical masks is reported to be lower compared to N95 respirators in a crossover trial of healthy volunteers (Derrick and Gomersall 2005).

16.5.1.4 Use in Community Settings during Outbreaks and Pandemics

Medical masks are recommended for the general public, although there is limited evidence around their effectiveness during outbreaks and pandemics. The RCTs conducted in community settings show that masks can protect people provided they are compliant, and provided the device is used early (MacIntyre and Chughtai 2015). During large outbreaks and pandemics, the focus may shift to delaying spread and reducing community transmission through population-based measures. Common interventions used to reduce the spread of epidemics in the community are quarantine and social distancing through closure of schools and workplaces and cancellation of nonessential public gatherings (Bell et al. 2006). However, the effectiveness of these interventions has not been quantified (Aledort et al. 2007), and there is an urgent need for research on the effectiveness of non-pharmaceutical public health interventions in the community.

16.5.2 Facemasks and Respirator Use for Biological Agents

Biological agents may be released accidently (e.g., in a laboratory) or deliberately (e.g., bioterrorism). In laboratory settings, technicians and scientists generally use PPE according to a predetermined biosafety level, and risk of transmission is less in such a controlled environment. However, the nature of the pathogen, transmission mode, and its concentration in the air would be unknown in the initial stage of a biological attack. In the event of a covert attack, the symptoms may appear late (i.e., after the incubation period) and hospital and other frontline workers might not get a chance to use PPE. Moreover, secondary transmission might have already been started in case of highly infectious pathogens, such as modified strains of influenza and smallpox.

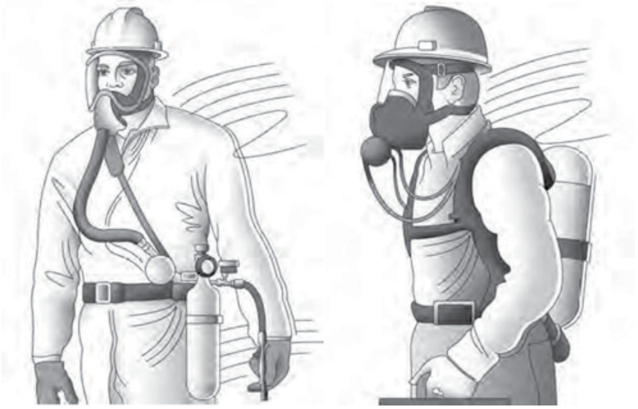
16.5.2.1 Selection of Respirators in a Bioterror Event

Biological agents are transmitted through various routes, making appropriate respiratory, skin, and eye protection required. The United States

Environmental Protection Agency (US EPA) has categorized PPE according to its level of protection (US EPA 2015). "Level A" is the highest level of protection and is used when maximum respiratory, skin, and eye protection is required. This includes SCBA, chemical and vapor protective suit, gloves, and boots. "Level B" protection includes SCBA and chemical resistant clothing, and is required when the highest level of respiratory protection and lesser skin protection is required. "Level C" and "level D" protections are lower levels of protection required for airborne and splash hazards, respectively (US EPA 2015).

The highest respiratory protection, such as SCBA or airline respirators (Figure 16.2), should be used if the biological agent is unknown, if an aerosol-generating device is used, and if the concentration of infective agent is very high in the air (CDC 2001, IOM 2006, OSHA 2009b, 2014). Air is supplied from an outer source in both types of equipment and the risk of inhalation is reduced significantly (ECRI 2002). SCBA supplies open- or closed-circuit air with positive pressure. In an open-circuit system, exhaled air is exhausted in the outer atmosphere, while in closed-circuit systems carbon dioxide is removed from the exhaled air and replaced with the oxygen. Air is supplied through a pump or a cylinder in case of airline respirators, and these products are suitable for work in small area such as isolation or decontamination room (ECRI 2002).

However, it may not be possible to select appropriate respiratory protection in case of sudden, covert, or unrecognized attack, which would be likely in case of bioterrorism. Many incidents have not been correctly recognized as bioterrorism in the past, so the detection of such events remains a challenge (MacIntyre 2015).



Full facepiece supplied-air respirator (SAR)

Full facepiece self-contained breathing apparatus (SCBA)

FIGURE 16.2
Supplied air and SCBA configurations. (Courtesy of Occupational Safety & Health Administration. U.S. Department of Labor Assigned Protection Factors for the Revised Respiratory Protection Standard. https://www.osha.gov/Publications/3352-APF-respirators.pdf.)

16.5.2.2 Training and Other Related Issues

Training should be provided on the correct use of air-supplying respirators which are not commonly used in healthcare and community settings. Incorrect use may harm the wearer as occurred in Israel during the Gulf war crisis when gas masks were provided to four million people (Hiss and Arensburg 1992). Despite the fact that instructions were provided to wearers, 13 people died of suffocation. Certain types of protective clothing are coated to provide protection against chemical hazards, so may cause heat stress. For this reason, a heat stress program is recommended for workers (ECRI 2002).

16.5.3 Industrial Products and Their Applications in Healthcare Settings

Many types of respirators are used in an industrial setting, and their applications in the healthcare setting have never been tested. PAPRs are more widely used in industrial applications, and there have been recent technological developments widely adopted in these markets which may have significant benefits for HCW protection. However, industrial PAPRs have not been tested in the clinical setting, and there is limited research on their practicality and comfort.

16.6 Case Studies

16.6.1 Case Study 1: Facemask and Respirator Use during Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV) Outbreak in 2002–2003

SARS-CoV is a single-strand RNA virus (Peiris et al. 2003a, Ling et al. 2011, CDC 2014d) and is known to cause infection in both humans and animals (Peiris et al. 2003b). The virus first emerged from the Guangdong Province in Southern China in November 2002 (Breiman et al. 2003) and spread to 29 countries within a short time resulting in 8096 probable cases and 774 deaths (WHO 2014d). The virus mainly transmits though direct contact with mucus membranes and droplets (Ling and Seto 2011). There is some evidence of airborne transmission of SARS as well (Yu et al. 2004, Chen et al. 2009). Moreover, the risk of transmission is reported to be increased during AGPs, particularly tracheal intubation, noninvasive ventilation, and tracheotomy (Fowler et al. 2004, Tran et al. 2012). Among the total 8096 SARS cases, 1706 (21%) were HCWs. In some countries, the percentage of infected HCWs among total cases was extremely high. For example, out of a total of 63 SARS cases in Vietnam, 36 (57%) were HCWs. Similarly, the proportion of HCWs, among the total SARS cases, was also high in Canada (43%), Singapore (41%), Hong Kong (22%), Taiwan (20%), and China (19%) (WHO 2014d).

Facemasks and respirators were commonly used by HCWs and the general public during the SARS outbreak in 2002–2003. Most of the studies showed that both facemasks and respirators were protective against SARS (Seto et al. 2003, Loeb et al. 2004, Teleman et al. 2004). Facemask use in Vietnamese hospitals was associated with low SARS transmission (Nishiyama et al. 2008). Some researchers argued that the outbreak in Vietnam was contained without high-level infection control measures such as negative pressure rooms and N95 respirators, and medical masks were considered sufficient (Nicolle 2003). A case control study in five hospitals in Hong Kong supported the use of medical masks for SARS (Seto et al. 2003). Studies in Singapore (Teleman et al. 2004), Canada (Loeb et al. 2004), and Taiwan (Lu et al. 2006) also support use of either facemask or respirators to protect from SARS.

On the other hand, facemasks and respirators were found not to be protective against SARS in other studies (CDC 2003, Chen et al. 2004, Lau et al. 2004, Park et al. 2004). Interestingly, a study in the United States reported 110 HCWs exposed to SARS patients, of whom 45 (44%) did not use a medical mask or respirator. No case of SARS was reported in those 45 HCWs (Park et al. 2004). Of 73 HCWs exposed to initial SARS cases in Taiwan, around half did not use any mask/respirator and were not infected (Chen et al. 2004). A study in Hong Kong also failed to find a difference in the use of N95 respirators between SARS cases and controls. However, masks and respirators were found protective when combined with other PPE (Lau et al. 2004). Similarly, a low rate of infection was reported from a public hospital in Vietnam, despite the fact that N95s were unavailable in the initial period of outbreak and other control measures were applied (Le et al. 2004).

Health organizations and countries have different recommendations regarding selection and use of facemasks and respirators for SARS (Chughtai et al. 2013b). During the outbreak, the WHO (2007) recommended facemasks in low-risk situations and respirators in high-risk situations, whereas the CDC (2004) recommended respirators in both low- and high-risk situations. The guidelines of most countries were in line with the CDC, for example, the United Kingdom (Health Protection Agency UK 2005), Canada (Health Canada 2003), Australia (Department of Health and Ageing and the Communicable Disease Network of Australia 2004), Pakistan (Ministry of Health Pakistan 2006), and Vietnam (Ministry of Health 2003) also recommend respirators to protect against SARS. There was also an inconsistency in the selection of respirator. The CDC and most countries prefer N95 or equivalent respirators in low-risk situations with SARS patients, while the United Kingdom recommends an FFR3 (Chughtai et al. 2013a,b).

The last case of SARS was reported by the WHO on 5 July 2003. Although a few cases occurred later in 2003 and 2004, they were due to breaches in laboratory biosafety and sporadic community-acquired infection. Fortunately, significant secondary transmission did not occur (Department of Communicable Diseases Surveillance and Response 2004). Since 2004, no new cases of SARS-CoV have been reported anywhere in the world. However in 2012, a novel coronavirus, Middle East respiratory syndrome coronavirus (MERS-CoV), emerged in the Middle East and spread to the United Kingdom and to a few other countries (Bermingham et al. 2012, Pollack et al. 2013). As of August 2017, more than 2000 laboratory-confirmed cases of MERS-CoV and 643 deaths have been reported to the WHO from 27 countries (WHO 2016a). There is the same controversy regarding the selection of respiratory protection for MERS. The WHO recommends medical masks for low risk and respirators for high risk (WHO 2016b), while the CDC recommends respirators in both situations (CDC 2015c). Most of the MERS cases were reported from Saudi Arabia and the Ministry of Health in Saudi Arabia also recommended respirators to protect from MERS (Scientific Advisory Council 2014).

16.6.2 Case Study 2: Facemask and Respirator Use during the Ebola Outbreak

Ebola is a filovirus and causes hemorrhagic fever in humans (WHO 2014e). Ebola was first reported in 1976 in the Democratic Republic of Congo, and since then sporadic cases and small-scale outbreaks have occurred in many central African countries (WHO 2015a). There are several strains of Ebola virus, but the Zaire strain commonly occurs in Africa and West Africa and can have a 90% case fatality rate (range 25%–90%). Fruit bats are considered as the natural reservoir and the disease transmits to humans through direct contact with other primates including monkeys, gorillas, and chimpanzees (Leroy et al. 2005). Human-to-human transmission of Ebola occurs predominantly though direct contact with blood and body secretions (Alimonti et al. 2014, WHO 2014e). There is some evidence of airborne transmission of Ebola as well (Dalgard et al. 1992, Johnson et al. 1995, Jaax et al. 1995, CNN 2014, Public Health Agency of Canada 2014).

Many issues were highlighted regarding the selection and use of PPE during the 2014 Ebola outbreaks in West Africa (MacIntyre et al. 2014a,b,c). As the predominant transmission mode of the Ebola virus is direct contact with blood and body fluids, the WHO, the CDC, and most countries initially recommended a medical mask with face shield to protect from Ebola (WHO 2008, CDC 2014e, MacIntyre et al. 2014b). These guidelines were challenged by researchers citing the high rate of infections among HCWs, low infective dose, high case fatality, and inconsistent recommendations for frontline workers and laboratory scientists (MacIntyre et al. 2014c). During the 2014 West African epidemic, the death toll for HCWs was high, with 1 in 10 (over 880) HCWs contracting Ebola. The case fatality rate was very high (around 90%) and infectious dose was very low. Initially, medical masks were recommended for frontline HCWs in unstable, contaminated, and unpredictable clinical environments, while respirators were recommended for the laboratory scientists who worked in highly controlled, sterile environments (Department of Health and Ageing Australia 2007, CDC 2014f).

The recommendations were subsequently changed by the CDC (but not the WHO) in favor of respirators and full body suits (MacIntyre et al. 2014b). Since then, the CDC and WHO have confirmed that PPE is an essential part of ensuring the occupational health and safety of HCWs caring for Ebola patients (MacIntyre et al. 2014b, WHO 2015b), and there has been a renewed focus on ensuring appropriate equipment and practices are in place.

The recent Ebola epidemic illustrated how vulnerable HCWs, and indeed the global community, are to infectious agents when healthcare policies are not well informed and updated (MacIntyre et al. 2014c).

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17

Efficacy of Face Shields against Cough Aerosol Droplets from a Cough Simulator

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17.1 Introduction

Sprays and splashes of fluids containing infectious microorganisms present an occupational hazard for healthcare workers. Droplets of these fluids can be inhaled, land on broken skin, or deposit on mucus membranes in the mouth, nose, or eyes. Once there, the pathogens they carry may infect workers and cause illness. For this reason, the U.S. Healthcare Infection Control Practices Advisory Committee (HICPAC) recommends that a mask and eye protection be worn "during procedures and patient care activities likely to generate splashes or sprays of blood, body fluids, [or] secretions … " (Siegel et al. 2007). However, although the requirement to wear a face shield or goggles while performing aerosol-generating procedures is well established, the need for such equipment to protect healthcare workers during routine care of patients with respiratory infections is the subject of debate. The current HICPAC guidelines explicitly recommend wearing a face shield or goggles during all patient care for certain illnesses such as severe acute respiratory syndrome (SARS) and avian influenza (Siegel et al. 2007). For other infections that may be spread by respiratory aerosol droplets, HICPAC recommends wearing a face mask but states that it has "no recommendation for routinely wearing eye protection (e.g., goggle or face shield), in addition to a mask, for close contact with patients who require Droplet Precautions. [This is an] unresolved issue" (Siegel et al. 2007).

One reason for the controversy surrounding a recommendation to wear goggles or a face shield while treating patients with respiratory infections is that little is known about the potential exposure to pathogen-laden droplets from these patients and the efficacy of different types of protective measures. This is particularly true for aerosols produced during coughing, which is one of the most common symptoms of respiratory tract infections. Coughing helps clear the airways of mucus and remove excess fluids from the lungs, especially when normal mechanisms of mucociliary clearance are impaired (McCool, 2006). During a cough, droplets of airway secretions can become airborne and be expelled from the mouth in a high-velocity aerosol plume. The aerosol droplets generated during coughing span a broad size range, from tens of nanometers to hundreds of micrometers, and the dispersion of these droplets in the environment depends to a large degree upon their size (Nicas et al. 2005, Gralton et al. 2011). Small-aerosol droplets from a coughing patient can remain airborne and spread throughout a room, and can easily be inhaled by a healthcare worker (Lindsley et al. 2012a, Noti et al. 2012). The potential for larger droplets to settle onto surfaces, impact on the face or eyes, or to be inhaled, is not as well studied, and many questions remain. In early work, Wells (1934) estimated that droplets with a diameter of 100 μm or more will tend to settle rapidly on the ground before evaporating, while smaller droplets will evaporate and become "droplet nuclei," remaining airborne much longer. Nicas et al. (2005) later revised this with newer data on the composition of respiratory fluids and concluded that particles need to have initial diameters less than 20 μm in order to become droplet nuclei. In an early photographic study, Jennison (1942) found that the majority of visible droplets produced during coughing and sneezing travel only 2–3 feet from the mouth, but that some were able to travel much further. Using a numerical model, Xie et al. (2007) calculated that droplets as large as 200 μm could travel 1.5 m from a coughing patient before settling. In an experimental study, Hamburger and Robertson (1948) showed that most bacteria from human sneezes were detected in droplets that settled within 1.5 feet of the test subject, but that some droplets settled as far as 9.5 feet away. Bischoff et al. (2013) collected aerosol samples in hospital rooms with influenza patients; they found that influenza-laden particles with diameters greater than 4.7 μm could be found 6 feet away from the patient, but that the amount of virus detected was much lower than at closer distances.

Face shields are one option for protecting the face from pathogen-laden droplets. Although they are more bulky than goggles or safety glasses, face shields offer the advantage of guarding the entire face from contamination (NIOSH 2013). Some workers also may find face shields more comfortable or find that they fit better over eyeglasses or respirators. Several studies have examined face shields after use during surgeries or other aerosol-generating medical and dental procedures as a way of demonstrating that an exposure risk exists and that face shields provide protection. These studies found that many or most of the face shields worn by healthcare workers had splatters of blood or other fluids and that this contamination frequently went unnoticed (Kouri and Ernest 1993, Collins et al. 2000, Endo et al. 2007, Ishihama et al. 2008, Wines et al. 2008). However, although these studies clearly demonstrate that face shields can intercept droplets traveling toward the face, they do not indicate which sizes of aerosol droplets are blocked and which are able to travel around the shield to be inhaled or deposited on the face. In addition, the studies all examined procedures in which significant droplet generation was expected, but none looked at potential exposure to aerosols from coughing patients with respiratory infections, about which less is known. During the 2009 H1N1 influenza pandemic, the Centers for Disease Control and Prevention (CDC) recommended that healthcare workers consider using face shields to reduce the surface contamination of respirators (CDC 2013). However, no data have been published showing how much exterior deposition of pathogens occurs or how effectively face shields decrease it. In its 2011 report on preventing transmission of pandemic influenza, the Institute of Medicine (IOM) urged the National Institute for Occupational Safety and Health (NIOSH) and other organizations to "investigate the effectiveness of face masks and face shields in preventing transmission of viral respiratory diseases" (IOM 2010).

The purpose of this study was to quantify the exposure of healthcare workers to cough aerosol droplets while working close to a patient and to examine the efficacy of face shields in reducing this exposure. Our results provide a better understanding of the health risks posed by infectious droplets produced by coughing patients and of the appropriate protective equipment in these situations. This work should assist the occupational and public health communities in providing research-based recommendations for effective strategies for the protection of workers in healthcare settings.

17.2 Methods

17.2.1 Influenza Virus Culture

Madin-Darby canine kidney (MDCK) cells (ATCC CCL-34) and influenza strain A/WS/33 (H1N1, ATCC VR-825) were purchased from the American Type Culture Collection (ATCC, Manassas, VA) and maintained as described previously (Blachere et al. 2011). The influenza virus was propagated in complete Dulbecco's modified Eagle medium (CDMEM) consisting of Dulbecco's modified Eagle medium, 100 U/mL penicillin G, 100 μg/mL streptomycin, 2 mM L-glutamine, 0.2% bovine serum albumin, and 25 mM 4-(2-hydroxyethyl)-1-piperazineethanesulfonic acid (HEPES) buffer (Life Technologies, Grand Island, NY).

17.2.2 Exposure Simulation Chamber

A schematic of the experimental setup is shown in Figure 17.1. Experiments to simulate the exposure of a healthcare worker to the aerosol droplets produced by a coughing patient were conducted in a 3.2 m long × 3.2 m wide × 2.3 m high environmental chamber (Noti et al. 2012). The room included a high efficiency particulate air (HEPA) filtration system to remove airborne particles before and after testing and an ultraviolet germicidal irradiation system to disinfect the chamber after the influenza virus was used. During the experiments, the chamber was sealed and the filtration system was off, so that no air exchange or filtration occurred. The cough aerosol simulator, breathing simulator, and aerosol particle measurement instruments were controlled from outside the exposure chamber. During the aerosol particle measurement experiments, the chamber temperature was 24°C (standard deviation [SD] 1.4°C) and the relative humidity was 21% (SD 5.9%). During the experiments using influenza virus, the chamber temperature was 24°C (SD 1.3°C) and the relative humidity was 23% (SD 3.3%).

17.2.3 Cough Aerosol Simulator

The cough aerosol simulator used in these experiments has been described in detail previously (Lindsley et al. 2013). The test aerosol was generated by aerosolizing CDMEM alone for the aerosol particle measurement experiments, and CDMEM containing the influenza virus for the influenza virus experiments. For some experiments, an air brush (Model 200, Badger Air-Brush Co., Franklin, IL) was used to produce a cough aerosol with a volume median diameter (VMD) of 8.5 μm and a geometric standard deviation (GSD) of 2.9 (referred to here as the "large-particle cough aerosol"). For other experiments, a micropump nebulizer (Aeroneb AG-AL7000SM, Aerogen, Galway, Ireland) was used to produce an aerosol with a VMD of 3.4 μm and a GSD of 2.3 (small-particle cough aerosol). For both aerosol generators, the total volume of the aerosol expelled during each cough was approximately 68 μL. As described previously, the cough volume and amount of the influenza virus expelled in each cough were considerably larger than those reported for human coughs (Lindsley et al. 2013). This was necessary to allow detection of the airborne particles and influenza virus after the particles dispersed in the test chamber. The cough air flow was produced by a metal bellows driven by a computer-controlled linear motor. It was based on coughs recorded from

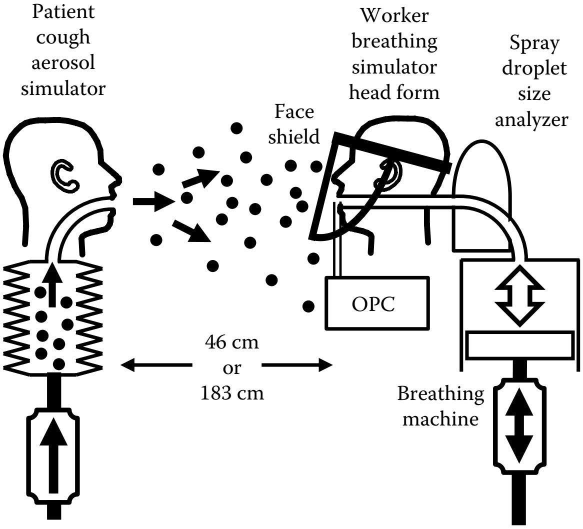
Patient cough aerosol simulator
Worker breathing simulator head form
Spray droplet size analyzer
Face shield
OPC
46 cm or 183 cm
Breathing machine

FIGURE 17.1
Schematic of the experiment using particle spectrometers. The mouth of the cough aerosol simulator and the mouth of the breathing simulator were 152 cm (60 inches) above the floor and 46 cm (18 inches) or 183 cm (72 inches) apart. For experiments using the influenza virus, the OPCs and the droplet size analyzer were not used, and a respirator was sealed to the breathing head form to act as a filter to collect the virus that was inhaled.

influenza patients and had a volume of 4.2 L and a peak flow rate of 11.4 L/s. The coughing and breathing simulators were synchronized so that each cough was initiated at the start of an inhalation by the breathing simulator.

17.2.4 Breathing Simulator

A digital breathing machine (Warwick Technologies Ltd., Warwick, UK) with a standard medium-sized head form (Sheffield model 189003, ISI, Lawrenceville, GA) was used to simulate a respiring healthcare worker. The breathing waveform was sinusoidal, with a flow rate of 32 L/min. For experiments using the influenza virus in the cough aerosol, an N95 respirator was used as a collection filter for virus-laden particles that were inhaled by the breathing simulator. When a respirator collection filter was used, it was sealed to the head form with adhesive, and the respirator was tested for leaks with a standard respirator fit testing device (Model 8038 PortaCount Pro Plus, TSI, Shoreview, MN). The head form was cleaned after experiments with the influenza virus to disinfect it and to prevent transfer of residual virus to subsequent respirators.

17.2.5 Aerosol Particle Concentration Measurements

Two different types of instruments were used to measure aerosol concentrations. A spray droplet size analyzer (Spraytec Analyzer with a 300-mm lens and an Inhalation Cell, Malvern Instruments Ltd.) was attached behind the breathing head form so that the concentration of aerosol particles inhaled during breathing could be measured (Figure 17.1). In addition, two optical particle counters (OPCs; Model 1.108, Grimm Technologies, Inc., Douglasville, GA) drew aerosol samples through vertical 16 cm × 3 mm inner-diameter stainless-steel tubes with inlets located 4.4 cm to the left and right of the mouth of the breathing simulator (Figure 17.1). When face shields were tested, the tube inlets were behind the face shield (i.e., between the face shield and the head form). A more detailed discussion of the capabilities and limitations of these instruments in our experiments is given in the supplemental material.

17.2.6 Detection of Influenza Virus

For experiments using influenza virus, when the cough exposure and collection portion of the experiment was completed, the respirator collection filter was removed and four round 25-mm coupons were punched from it. The coupon locations were distributed across the front and side of the respirator to accommodate any variations in virus distribution on the respirator. The outermost layer of each coupon (referred to here as the "outer layer") was separated from the middle and inner layers (referred to collectively as the "inner layers"), and the influenza virus was eluted from each coupon layer by overnight incubation in 2 mL of supplemented Hank's Balanced Salt Solution (HBSS) (Blachere et al. 2011). Virus was eluted from the face shields by cutting each shield into eight sections, rolling the pieces into cylinders, placing the eight pieces sequentially in a 50-mL centrifuge tube with 5 mL of modified HBSS, and vortexing vigorously. Viral RNA was isolated from an aliquot of the elution medium, and the number of copies of the virus present in each sample was determined with quantitative real-time polymerase chain reaction (qPCR) (Blachere et al. 2011). For the short-range experiments with the large-particle cough aerosol, viral plaque assays (VPAs) were performed to determine the amount of the viable influenza virus recovered (Blachere et al. 2011).

17.2.7 Data Analysis

For the experiments performed with the aerosol particle measurement instruments, the parameters studied were the presence or absence of a face shield, the distance between the simulators (46 or 183 cm), and the cough aerosol particle size distribution (large or small). The experiments performed with the influenza virus had the same experimental parameters, with the addition of the collection time (5 min or 30 min).

For the data from the spray analyzer, the volume of aerosol inhaled by the breathing simulator was estimated by integrating the aerosol volume concentration and the breathing flow rate for 1.4 s after the cough (corresponding to the inhalation part of the first breathing cycle after the cough). The mean and SD of six experiments were calculated for each particle size bin, and the results were also summed over all of the size bins to get the total volume of inhaled aerosol. The volumes of particles inhaled during use of a large-particle cough aerosol versus a small-particle cough aerosol were compared by means of student's *t*-test.

Since the OPCs measure the optical diameter and the number of airborne particles, the optical diameter was used to calculate an estimated particle volume based on the center diameter of each size bin, and the particle count data were then used to estimate the total volume of the aerosol in each size bin. The volume of aerosol inhaled by the breathing simulator from 1 to 29 min after each cough was determined by integrating the volume concentration and the breathing rate (32 L/min) over time. For the OPC results, the effects of the use of a face shield, the cough aerosol particle size distribution, and the distance from the coughing to the breathing simulator on the total volume of particles inhaled were compared by means of an analysis of variance (ANOVA), with these three parameters treated as fixed effects. All main effects and two-factor interactions were tested. This procedure was also used to evaluate the OPC results for the VMD of the inhaled particles.

For the experiments using influenza virus, an N95 respirator was used as a collection filter for inhaled particles. Thus, we assumed that the simulated worker would have been exposed to any influenza virus found on the respirator if the respirator had not been worn. The four coupons taken from each respirator had an area of 4.9 cm^2 each, whereas the entire respirator had an area of 137 cm^2. Thus, the number of influenza virus copies found on the respirator coupons was multiplied by 6.98 to estimate the amount of virus on the entire respirator. Similarly, the area of the face shield was 548 cm^2, of which 442 cm^2 was used in the analyses, and so the number of virus copies found on the face shield sections was multiplied by 1.24. The qPCR results for the number of viruses inhaled and the amount of virus deposited in the different layers of the respirator were analyzed by means of an ANOVA, in which the use of a face shield, the distance, the cough particle size, the collection time, and the amount of virus deposited on each layer were treated as fixed effects. All main effects and the interaction between the use of a face shield and the layer deposition were tested. Differences were considered significant at a p value of ≤ 0.05.

17.3 Results

17.3.1 Initial Exposure to Cough Aerosol Droplets

The size distribution of the aerosol inhaled during the first 1.4 s after a cough when the simulators were 46 cm apart and a face shield was not worn is

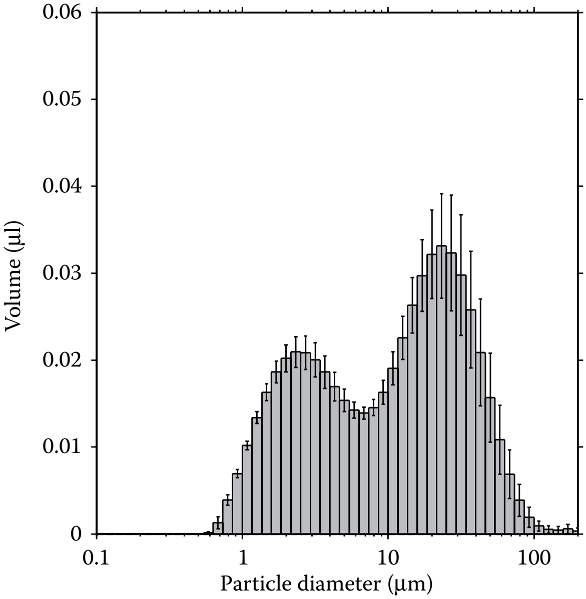

FIGURE 17.2
Volume size distribution of the particles inhaled by the breathing simulator in 1.4 s after a single large-particle cough. The mouths of the coughing and breathing simulators were 46 cm apart, and the breathing simulator was not wearing a face shield. The plot is the average of six coughs. The error bars show the SD.

shown in Figure 17.2 for the large-particle cough aerosol. The inhaled aerosol particles had a total volume of 0.58 μL, a VMD of 9.5 μm, and a GSD of 3.4. For the small-particle cough aerosol, the size distribution of the inhaled particles is shown in Figure 17.3. In this case, the total volume of the inhaled particles was 0.52 μL, with a VMD of 2.1, and a GSD of 2.0. The difference in the total inhaled volume approached statistical significance ($p = 0.069$). However, although the volume of small-particle cough aerosol inhaled during the first 1.4 s was lower than that of the large-particle aerosol, the concentration of the inhaled small-particle aerosol cloud typically remained high enough to be in the detection range of the spray analyzer for several seconds longer than did the large-particle aerosol. Therefore, it is likely that the difference in the total volume of aerosol inhaled was not significant.

The inhaled aerosol concentration was within the detection range of the spray analyzer only during those experiments in which the coughing and breathing simulators were 46 cm apart and no face shield was worn by the breathing simulator, and only during the first few seconds after a cough. For all other experiments, the concentration was below the detection threshold for the entire cough, and thus it was not possible to use the results from the spray analyzer to compare the effects of wearing or not wearing a face shield or increasing the distance between the simulators.

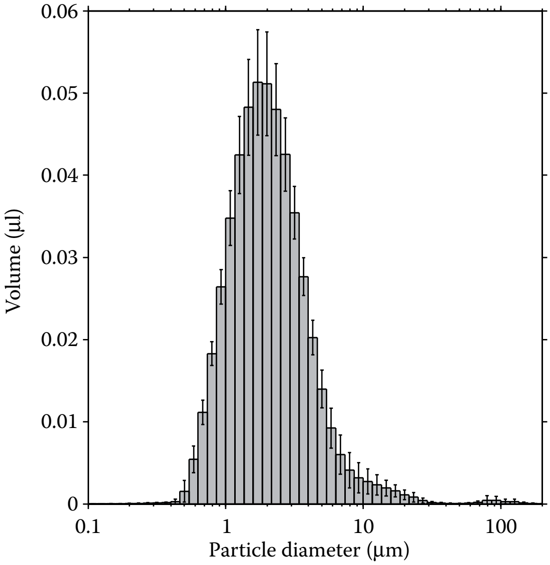

FIGURE 17.3
Volume size distribution of the particles inhaled by the breathing simulator in 1.4 s after a single small-particle cough. The mouths of the coughing and breathing simulators were 46 cm apart, and the breathing simulator was not wearing a face shield. The plot is the average ± SD of six coughs.

17.3.2 Long-Term Exposure to Cough Aerosol Droplets

During use of the OPCs, the aerosol particle concentration exceeded the upper aerosol concentration limit of the instruments for up to 50 s after each cough. For this reason, the first minute of aerosol concentration data from these instruments could not be used, and the analysis was limited to data collected from 1 to 30 min after each cough. Exposure to the cough aerosol was characterized by an initial spike in concentration, followed by lower levels as the aerosol particles dispersed and settled over time. This can be seen in Figure 17.4 for the large-particle cough aerosol and in Figure 17.5 for the small-particle cough aerosol. The total volume of the aerosol particles inhaled by the breathing simulator under each test condition during the period from 1 to 30 min after the cough can be seen in Figure 17.6. Wearing a face shield significantly reduced the amount of cough aerosol that was inhaled by the breathing simulator, while increasing the distance between the coughing and breathing simulators increased the aerosol inhalation during the 1–30 min time period ($p < 0.001$ for both). A greater volume of cough aerosol particles was inhaled during experiments using the small-particle aerosol than those using the large-particle aerosol ($p < 0.001$). Significant interactions occurred between face shield use and distance ($p = 0.017$), face shield use and cough aerosol particle size ($p = 0.007$), and particle size and

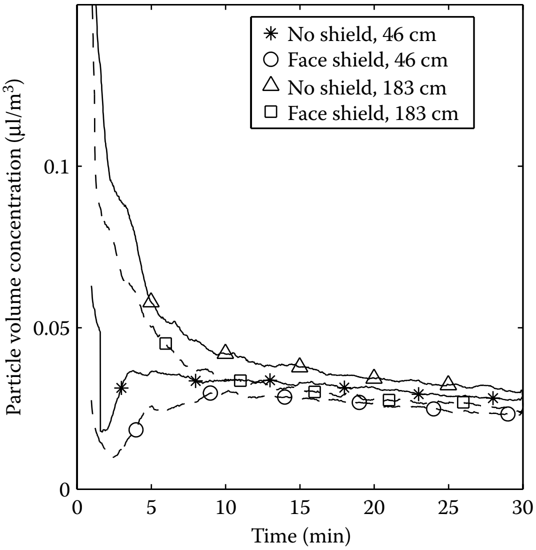

FIGURE 17.4
Volume concentration of airborne particles at the mouth of the breathing simulator from 1 to 30 min after a single large-aerosol particle cough. The plots are restricted to 1–30 min after the cough because the aerosol concentration exceeded the upper limit of the instrument during the first 50 s. Each line is the average of three tests. The lines were smoothed with a 61-point running average. Every 300th point is marked with a symbol to aid in distinguishing the lines.

distance ($p = 0.006$). The VMD of the inhaled aerosol is shown in Figure 17.7. Donning a face shield or increasing the distance between the simulators did not have a significant effect on the VMD ($p = 0.702$ and 0.505), and none of the interactions between factors were significant.

17.3.3 Exposure to Influenza Virus

The amount of the influenza virus that was inhaled by the breathing simulator and deposited on the face shield under different test conditions is shown in Figure 17.8. Wearing a face shield and increasing the distance from the coughing to the breathing simulator both significantly reduced the amount of inhaled virus ($p < 0.001$ and $p = 0.009$), whereas changing the cough aerosol particle size or the collection time did not ($p = 0.520$ and 0.412). When the face shield was worn, the total amount of the virus that was deposited on both the respirator and the face shield combined was also significantly less than the amount deposited on the respirator alone when the face shield was not worn ($p = 0.001$). The fraction of the influenza virus that was detected on the inner layers of the respirator compared to the total collected in all layers is shown in Figure 17.9. Employing a face shield significantly decreased the amount of virus that was deposited on the outer layer relative to the inner

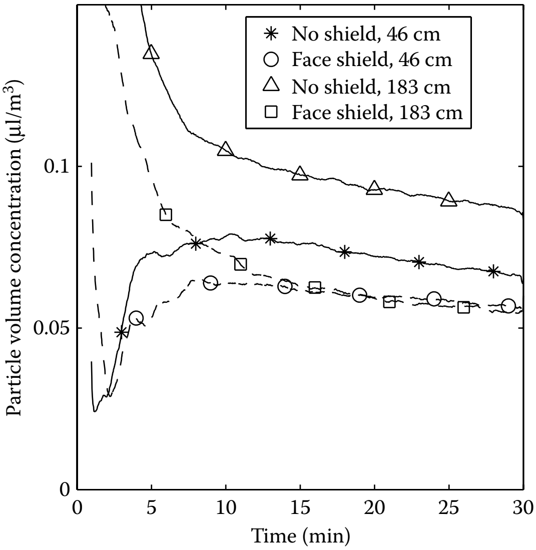

FIGURE 17.5
Volume concentration of airborne particles at the mouth of the breathing simulator from 1 to 30 min after a single small-aerosol particle cough. Each line is the average of three tests. The lines were smoothed with a 61-point running average. Every 300th point is marked with a symbol to aid in distinguishing the lines.

layers of the respirator ($p < 0.001$). The amount of the viable influenza virus recovered from the respirator and the face shield is shown in Figure 17.10. The use of a face shield reduced the amount of the viable virus on the respirator by 70%, although the difference was not statistically significant ($p = 0.189$).

17.4 Discussion

The exposure of healthcare workers to aerosol droplets while performing routine care of patients with respiratory infections is not well characterized. The efficacy of different types of personal protective equipment such as face shields against these aerosols when working at close range is also unclear. The purpose of this study was to gain a better understanding of the behavior of short-range cough aerosols, the potential risks they pose to healthcare workers, and the efficacy of face shields in reducing exposure.

The large- and small-particle cough aerosols from the cough simulator have a total particle volume of about 68 μL (Lindsley et al. 2013). Using the spray analyzer on the breathing simulator, we found that about 0.9% of the large-particle cough aerosol and 0.8% of the small-particle cough aerosol was inhaled by the breathing simulator immediately after a cough when no face shield was worn

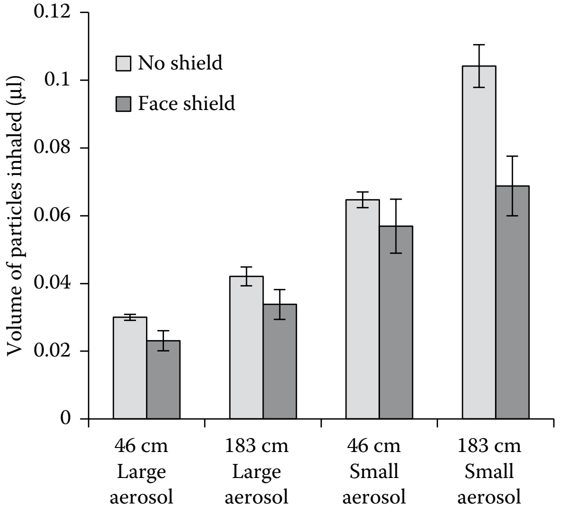

FIGURE 17.6
Volume of aerosol particles inhaled by the breathing simulator from 1 to 30 min after a single cough. Each bar is the average ± SD of three experiments.

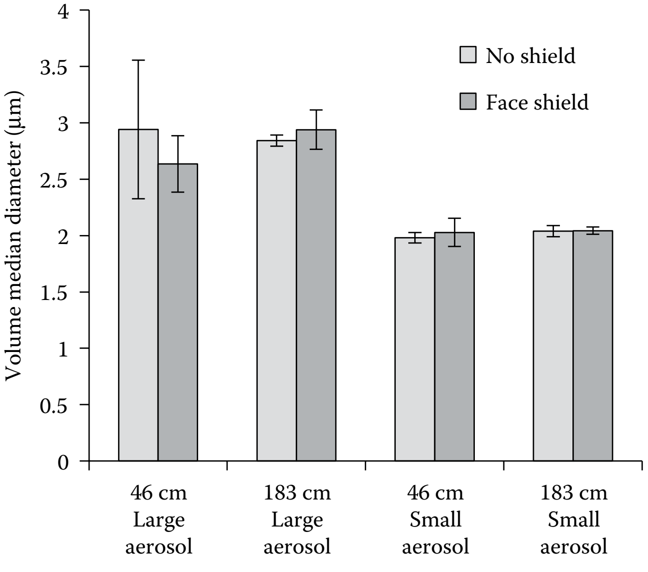

FIGURE 17.7
VMD of aerosol particles inhaled by the breathing simulator from 1 to 30 min after a single cough. Each bar is the average ± SD of three experiments.

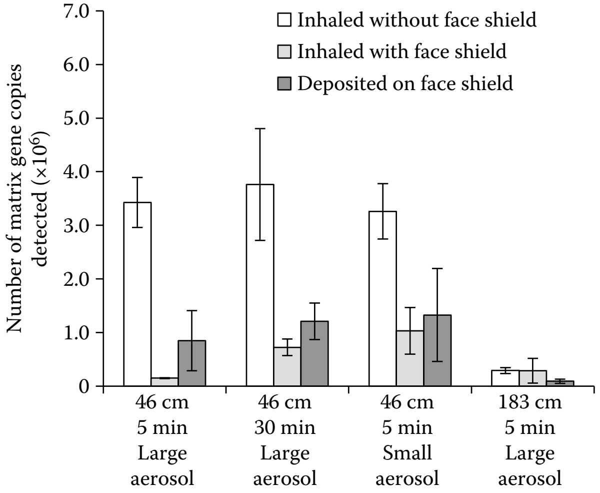

FIGURE 17.8
Number of influenza virus copies inhaled by the breathing simulator or deposited on the face shield after a single cough. Each bar is the average ± SD of three experiments.

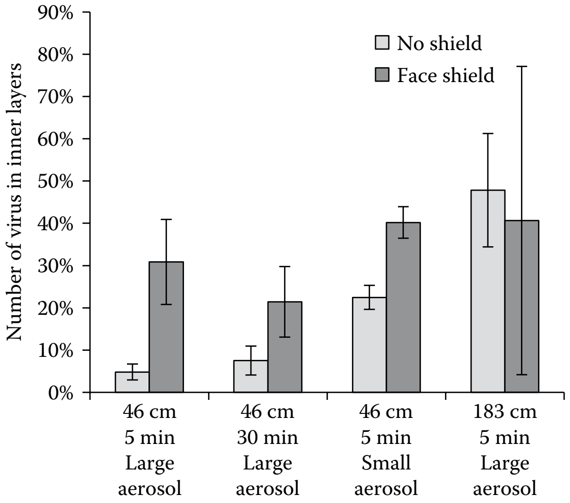

FIGURE 17.9
Amount of influenza virus that was detected in the inner layers of the respirator, compared to the total amount detected in all layers. These results are plotted as a ratio for ease of interpretation, but it should be noted that the absolute amount of virus collected at 183 cm was significantly less than collected at 46 cm (see Figure 17.8). Each bar is the average ± SD of three experiments.

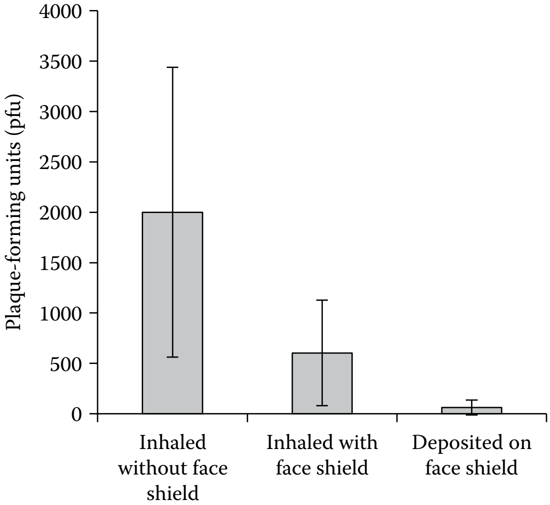

FIGURE 17.10
Amount of the viable influenza virus inhaled by the breathing simulator or deposited on the face shield 5 min after a single large-aerosol particle cough. The coughing and breathing simulators were 46 cm apart. Each bar is the average ± SD of three experiments.

and the simulators were 46 cm apart. The situation modeled here was a "worst-case" scenario, since it assumed a patient is coughing directly into the face of a healthcare worker at close range while the worker is inhaling. Nevertheless, these results do demonstrate the risk that a substantial exposure to respiratory fluid aerosols can occur very quickly when the caregiver is close to the patient.

The exposure measurements immediately after the cough were made while the cough aerosol particles were moving rapidly (the air velocity at the mouth of the coughing simulator peaks at about 32 m/s). This aerosol included particles up to 100 μm in diameter, many of which would be expected to settle quickly after leaving the mouth (a 50-μm particle with a density of 1 g/cm^2 will fall 1 m in about 13 s). On the other hand, the long-term exposure measurements were made during the period from 1 to 30 min after the cough, when the cough air flow had dissipated and the aerosol included mainly smaller particles that were able to remain airborne for an extended time and could flow more easily around a face shield. Consequently, using the face shield only caused a modest decrease in the inhalation of airborne particles over the long term (Figure 17.6). The results also indicate that the long-term exposure to the cough aerosol particles was actually somewhat higher when the breathing simulator was further from the coughing simulator than when it was closer (183 vs. 46 cm). This may seem counterintuitive, especially given the results from the spray analyzer, but in fact this outcome reflects the dynamics of the movement of the cough aerosol over a longer time frame and the fact that the long-term exposure measurement does not include the first minute of the cough. When the coughing and breathing simulators were close together, the cough aerosol was concentrated in a fast-moving plume that quickly swept past the breathing simulator and was replaced by cleaner entrained air from the surrounding environment. On the other hand, when the coughing and breathing simulators were further apart, the cough aerosol plume broadened and slowed down before reaching the breathing simulator and thus remained in the vicinity longer. The difference in concentration decreased over time as the aerosol dispersed more evenly throughout the room (Figures 17.4 and 17.5).

It is interesting to compare the volume of the particles that were inhaled immediately after a cough to those inhaled from 1 to 30 min after the cough, although three important caveats must be noted. First, the two instruments used different measurement methods. Second, the spray analyzer directly measured a region within the aerosol cloud, whereas the OPC drew a sample of the aerosol. Third, the spray analyzer measured the aerosol immediately after the cough, when many of the droplets were still wet, while the OPC measured particles that had time for evaporation and thus may have been smaller and more concentrated. Because of these limitations, the measurements must be compared cautiously, but they do suggest that the volume of aerosol inhaled during the first few seconds was about an order of magnitude larger than the quantity inhaled over the next 29 min.

The amount of the influenza virus inhaled by the breathing simulator was substantially reduced by the use of a face shield. This effect was most pronounced for the large-particle cough aerosol when the simulators were 46 cm apart and the virus was collected for 5 min after a cough. In this case, the amount of virus on the respirator was 96% lower when a face shield was worn. Similar results for the inhalation of the viable influenza virus were seen with the VPAs, although the lower sensitivity of the VPA relative to PCR produced results that were less conclusive. After 30 min, the amount of virus collected when a face shield was worn was reduced by 81%, which suggests that over the long term the face shield has less of a protective effect because smaller particles are able to flow around it and accumulate over time. Similarly, the face shield also was less effective against the small-particle cough aerosol; virus deposition was reduced by only 68%, again because small particles are better able to travel around the face shield and be inhaled.

Extending the collection time from 5 to 30 min increased the virus collection without a face shield by only 10%, which demonstrates that most of the virus deposition occurred immediately after the cough. This is consistent with findings from comparing the volumes of inhaled particles with use of the spray analyzer and OPCs, as discussed earlier. Increasing the distance between the simulators to 183 cm decreased the amount of virus inhaled by 92%, and the amount of virus collected was virtually the same with or without a face shield. These results indicate that, over the longer distance, the larger particles tended to slow down and fall toward the ground before they could reach the breathing simulator, while the smaller particles were able to traverse this distance and be inhaled. Note that the influenza virus collection occurred from

0 to 5 min after each cough, when large particles were collected. On the other hand, the particle counter results discussed above covered the time from 1 to 30 min after a cough, when the large particles were no longer airborne. This difference in large-particle collection explains why the particle counter results showed an increase in particle inhalation when the distance increased, while the influenza virus results showed a decrease in virus collection when the distance increased. An examination of the amount of virus deposited on the different layers of the respirator also shows that smaller particles are better able to evade a face shield. Larger aerosol particles are more likely to deposit on the outer layer of the respirator, while smaller particles are more likely to reach the inner layers. The use of a face shield reduced the fraction of the virus that deposited in the outer layer relative to the inner layers, which suggests that the aerosol reaching the respirator had a smaller average size.

As noted in the Introduction, during the 2009 H1N1 influenza pandemic the CDC recommended that healthcare workers consider using face shields to reduce the surface contamination of respirators (CDC 2013). Our results suggest that this would in fact be an effective strategy. In the large-particle cough experiments where the simulators were 46 cm apart and collection occurred for 5 min, the amount of the influenza virus that was deposited on the outer mask layer was reduced by 97% when a face shield was worn. In fact, because our cough simulations were limited to aerosol particles up to 100 μm, the reduction in external contamination would likely be much greater in cases where patients were producing coughs or sneezes with larger spray droplets. For the small-particle cough aerosol, the surface contamination was reduced by 76%, again showing that face shields are most protective against larger particles.

Finally, the limitations of this study need to be acknowledged. First, aerosol measurements of human coughs show tremendous variation from person to person in the quantity and size distribution of the aerosol particles and the amount of pathogens that are expelled (Escombe et al. 2008, Lindsley et al. 2010, 2012b, Gralton et al. 2011, Jones-Lopez et al. 2013). For this reason, it is impossible to define any particular cough aerosol profile as being representative of a human cough. Although the cough simulator generates aerosol outputs that are similar to human coughs (Lindsley et al. 2013), they are only two possibilities among a multitude of potential human cough aerosol expulsions, and other cough profiles may produce different results. Second, the concentration of the influenza virus in the cough aerosol from the simulator is likely to be about the same for droplets of all sizes, since the virus is dispersed in the test medium. This is unlikely to be the case for human cough aerosols because pathogens such as influenza are not uniformly distributed through the respiratory tract, and this distribution probably also varies with different microorganisms. Third, it is not clear why a bimodal distribution (double peak) was seen in the inhaled large-particle cough aerosol results from the spray analyzer. The bimodal distribution was consistently present in the results for all coughs; the peak at the larger particle size generally dominated during the initial part of the cough and inhalation, while the peak at the smaller size dominated later in the cough (data not shown). Until this aspect of the results is better understood, it should be interpreted with caution. Fourth, the test chamber was sealed so that no air exchange or filtration occurred during the experiments. Air filtration or exchange would be expected to reduce the long-term exposure to airborne particles, and room air-flow patterns could also affect exposure (Lindsley et al. 2012a). Finally, these experiments were conducted with the breathing simulator and the face shield facing directly toward the coughing simulator. Although this is probably the most common situation, it is not difficult to imagine scenarios where, for example, the head of a healthcare worker might be tilted up or sideways, away from a supine patient, in order to examine a monitor or adjust an IV bag. In that case, a cough could easily enter below or from the side of the face shield and impinge more directly on the face of the worker.

17.5 Conclusions

The possible risks to healthcare workers from exposure to cough-generated aerosols during routine patient care are not well characterized. Although it is agreed that workers need respiratory protection while treating patients with certain diseases that are known to be transmitted by airborne particles, the utility of protective devices such as face shields under these conditions is less clear. Our results show that considerable exposures of workers to potentially infectious material can occur over very short time frames when they examine or treat a coughing patient at close range. The use of face shields can substantially reduce the short-term exposure of healthcare workers to larger infectious aerosol particles and can reduce contamination of their respirators. They are less effective against smaller particles, which can remain airborne for extended periods and can easily flow around a face shield to be inhaled. Thus, face shields can provide a useful adjunct to respiratory protection for workers caring for patients with respiratory infections. However, they cannot be used as a substitute for respiratory protection when it is needed.

Acknowledgments and Disclaimer

The authors thank David H. Edgell, of the National Institute for Occupational Safety and Health (NIOSH), for manufacturing parts for the cough aerosol simulator.

The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the National Institute for Occupational Safety and Health.

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Section VI

Respiratory Protection for Emergency Responders

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18

Respiratory Protection for Medical First Responders and Receivers

Jan Schumacher

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18.1 Introduction

Protection from chemical or biological warfare agents has traditionally been considered a challenge for the armed forces. However, the possibility of mass casualties caused by chemical or biological terrorism is now regarded as a threat for our public health system.

Anesthesiologists, emergency doctors, and intensivists would be some of the first people to treat casualties affected by and contaminated with chemical/biological warfare agents (Baker 2002, 2004; de jong 2003; White 2002). Over the last few years, many countries have updated their major incident plans for such scenarios (Kenar and Karayilanoglu 2006; Lockey and Davies 2003; Han et al. 1999; Laurent et al. 1999). Their aim is to improve preparedness for treating casualties after an attack with chemical/biological warfare agents or other weapons of mass destruction and mass injury (Kenar and Karayilanoglu 2006; Lockey and Davies 2003; Han et al. 1999; Laurent et al. 1999; Sardesai et al. 2002; Gould et al. 2004). During the deliberate release of the nerve agent sarin in five underground carriages in Tokyo in 1995, not only were a large number of unsuspecting civilians affected, but also emergency service personnel (Okumura et al. 1996). This was experienced on a large scale in a Tokyo medical center where 13 of the 15 attending doctors treating the sarin victims developed symptoms of secondary nerve gas intoxication (Nozaki et al. 1995). Another medical center in Tokyo reported that they had to treat 25 secondarily exposed emergency medical personnel as inpatients (Masuda et al. 1995). These attacks illustrated how an ill-prepared and ill-equipped disaster management system can become overwhelmed (Weinstein and Alibek 2003; Tokuda et al. 2006). The classic concept has always been that patients who have been exposed to highly toxic and persistent chemicals should be decontaminated before arrival at the treatment facility to avoid secondary exposure and transmission of the agent. However, if immediate individual life support and airway management are vital during such an incident, caregivers need appropriate protection. The lessons learnt from this and other disasters have now been implemented by the Hazardous Response Teams initiative of the British Department of Health. The new strategy is to not only equip and train emergency medical service personnel as first responders but also hospital doctors as first receivers with personal protection equipment to allow safe and effective treatment of casualties contaminated with chemical/biological warfare agents.

Following our medical care of the victims of the London bombings in 2005 our group started a serious of studies looking into respiratory protection for medical first responders and receivers. Due to the vicinity of St Thomas Hospital to London's Houses of Parliament and the Whitehall village we are equipped with appropriate facilities enabling us to decontaminate self-presenting CBRN victims before admitting them into the Emergency department. We currently use the NHS Respirex suit ensemble to give our staff the required level of personal protection during their care of contaminated patients.

Due to certain issues with that suit ensemble we started to look into the matter in a scientific way, searching for better options:

In part one, we compared the feasibility of bi-ocular versus panoramic visor air-purifying respirators (APRs) (Schumacher et al. 2008). Part two compares conventional APRs versus powered air-purifying respirators (PAPRs) (Schumacher et al. 2009). Part three studies the effects of conventional APRs versus loose-fitting PAPR hoods during the simulated emergency treatment of CBRN victims (Schumacher et al. 2013).

18.2 Part 1: Binocular versus Panoramic Visor APRs

During this project, we evaluated the specific influence of bi-ocular versus panoramic visor APRs on the simulated emergency treatment of victims

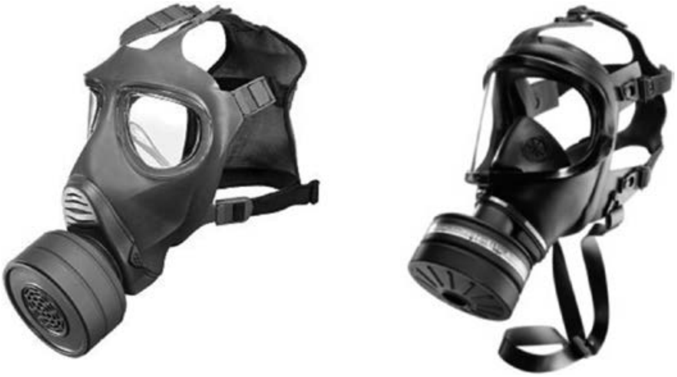

FIGURE 18.1
Respirator masks used in the study. Draeger M2000 (binocular visor) Draeger CDR4500 (panoramic visor).

contaminated with chemical warfare agents (Schumacher et al. 2008). Two different types of state of the art, full-face APRs were compared: the bi-ocular military M2000 and the panoramic visor civil defense respirator CDR4500 (both respirators by Draeger, Luebeck, Germany; Figure 18.1). The bi-ocular M2000 respirator is foldable and requires less storage and carrying space, the CDR4500 is more rigid due to the large polyamide panoramic visor. Both facepieces are made of a halo-butyl rubber compound and both systems feature speech membranes to improve communication.

The emergency scenario was carried out with the Emergency Care Simulator mannequin (ECS, Meti, Sarasota, USA) which can be intubated, cannulated, and defibrillated during simulated advanced life support (ALS) exercises. The mannequin was placed on a stretcher, and the acute arrival in the resuscitation area of the emergency department was mimicked (Figure 18.2).

At the start of the ALS scenario, the medical team donned their respirators and approached the simulator mannequin. After diagnosing unresponsiveness and apnea the first task (task 1) to be accomplished was the management of the airway by ventilation with an anesthetic circle system, aided by a Guedel oropharyngeal airway. In the meantime the assistant was applying the pulse oximeter, the ECG, and the BP cuff.

Task 2 involved the assistant connecting the IV infusion and administration of atropine, fentanyl, thiopentone, and rocuronium. The simulated anaesthetic drug application aimed firstly to achieve the best intubating conditions and secondly, to challenge the volunteers' handling of various syringes during drug administration. Task 3 was completed by the anesthesiologists after successful endotracheal intubation of the mannequin.

Task 4 consisted of the recognition of ventricular fibrillation requiring immediate paddle application, shock, and external chest compressions. We recorded the time until the first shock was given. In the final task (task 5), chest compressions were carried out for 60 seconds in each group.

TABLE 18.1
Treatment Times of Tasks

	Monitoring	IV Access and DA	ET Intubation	Defibrillation	Chest Compressions
Control	41 ± 8	18 ± 3	43 ± 3	20 ± 2	60
CDR4500	42 ± 4	18 ± 3	44 ± 4	22 ± 3	60
M2000	43 ± 4	21 ± 4	45 ± 5	20 ± 4	60

Mean ± *SD. n:* 22. (seconds), *DA*, Drug administration.

All anesthesiologists successfully accomplished the treatment objectives without any signs of discomfort, exhaustion, or breathing difficulties despite their unfamiliarity with APRs.

The overall treatment times were 122 ± 8 seconds for the controls, 126 ± 7 seconds for the panoramic visor mask, and 129 ± 8 seconds for the bi-ocular respirator [Mean ± SD]. The overall treatment times ranged from 110 to 146 seconds for the controls, 117 to 141 seconds for the panoramic visor mask, and 115 to 150 seconds for the bi-ocular respirator. The treatment times for the individual tasks are displayed in Table 18.1. We did not find any difference in treatment times between the groups under respiratory protection and the controls. The most time consuming task carried out was endotracheal intubation (43–45 seconds), notably with no failed attempts. The least time consuming task was the defibrillation (20–22 seconds). The calculation of effect sizes showed a weak effect in delaying treatment in the study group wearing the bi-ocular respirator. The data for different effect sizes are given in Figure 18.3.

Table 18.2 presents the results of the questionnaire. All participating anesthesiologists agreed that orientation with the panoramic visor respirator was better compared to the bi-ocular one (100%). The majority (88%) rated the fit of the foldable bi-ocular respirator as more comfortable. Breathing resistance was quoted as similar between the two respirator models (Table 18.2).

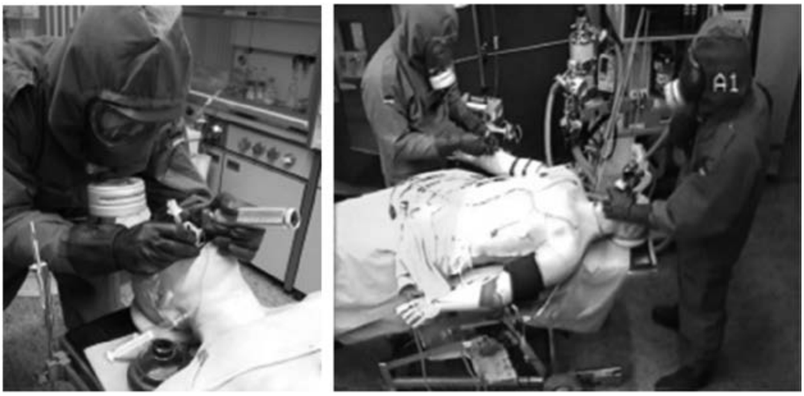

FIGURE 18.2
Intubation with M2000.

TABLE 18.2

Rating of the Respirator Qualities

	CDR4500	M2000
Visual Orientation	100	0
Breathing Resistance	50	50
Wearing Comfort	12	88

n: 22, (%).

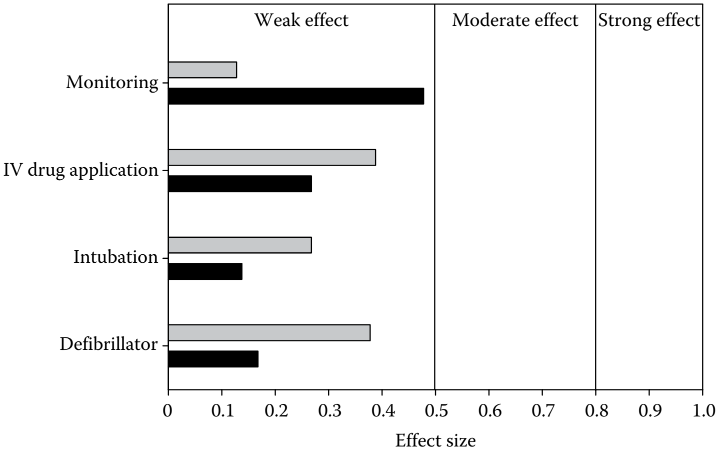

FIGURE 18.3
Effect sizes of possible treatment delay n: 22, gray bar: panoramic visor CDR-4500 respirator, black bar: bi-ocular M2000 respirator.

18.3 Discussion

Respiratory protection for medical first receivers like emergency physicians and anesthesiologists is of primary importance during the treatment of suspected chemical warfare agents' casualties. The risk of secondary intoxication applies specifically to nerve agents like sarin (Lee 2003; Evison et al. 2002; Gosden and Gardener 2005; Ben Abraham et al. 2002): Although rapid identification of the offending agent and swift decontamination before hospital admission are mandatory upstream process stages, medical personnel could become directly or indirectly exposed to chemical warfare agent's substances (Nozaki et al. 1995; Weinstein and Alibek 2003; Nakajima et al. 1997; US Army Medical Research Institute 2002). This might become more obvious if the substance release is widespread or a large number of casualties have to be cared for (Okumura et al. 1996; Nozaki et al. 1995). Residual nerve agent contamination of an individual's clothes may transfer a sublethal concentration to medical staff (Nozaki et al. 1995; Bradley 2000) possibly resulting in ocular signs and symptoms such as severe miosis, dim vision, and persistent rhinorrhea which can compromise the physician's ability to function (Okumura et al. 1996).

Taking these dangers of chemical warfare agent terrorism into account, the British Department of Health launched the new Hazardous Area Response Teams (HART) initiative in December 2006, in which paramedics are trained and equipped to provide prehospital life support in contaminated zones. Furthermore, a number of selected hospitals will be supplied and certain members of staff will be trained with personal protection equipment to enable a safe and effective treatment of casualties from an urban chemical warfare agent attack. Personal protection equipment is known to delay airway management and the provision of vascular access to a certain extent (Flaishon et al. 2004a,b; Vardi et al. 2004). Depending on the nature of the threat agent, there are two main components of individual protection that can be used singularly or in combination; respiratory protection and skin protection. Most chemical agents are capable of entering the body through the respiratory system, while some can penetrate intact skin. Therefore, from the occupational risk management perspective, respiratory protection has priority (WHO 2004). The most commonly used respiratory protection devices are air-purifying systems with the wearer drawing air through a filter (Martyny et al. 2002). Filters of APRs remove gases, vapors, and aerosols from the inhaled air. Their protective ability depends on the filter capacity and selectivity for various contaminants but they cannot protect against oxygen deficiency (WHO 2004; Martyny et al. 2002). APRs require a tight-fitting full-face mask, whereby the loss of peripheral vision and the increase of breathing resistance may have a significant effect on the wearer's function. A two lens respirator construction means that the mask can be temporarily folded in half longitudinally for compact stowage in a mask pouch. Due to this characteristic of compact stowage, bi-ocular respirators are preferred by the police and the military where mobility is of importance. For civil application, respirators with panoramic visors are favored, although the design is more rigid and space consuming.

The use of advanced medical simulation has become an accepted method for training and investigations on chemical warfare casualties (Vardi et al. 2004; Berkenstadt et al. 2003; Subbarao et al. 2006). The results of our scenarios demonstrated that sophisticated, state of the art, full-face APRs alone seem to have a negligible effect on the immediate short-term anaesthestic management of a single simulated chemical warfare agent victim. No previous studies have evaluated the sole impact of APRs on the functioning of anesthesiologists. Other investigators have either stressed the impaired dexterity of chemical protective gloves (Arad et al. 1993) or the heat load induced by the multi-layered over garments (Fine and Kobrick 1987). Visual field loss while wearing full-face respiratory protection is a well-perceived problem (Zelnick et al. 1994), especially in older models of bi-ocular, military-type respirators (McAlister et al. 1991). With the development of panoramic visor masks the nasal meridian is no longer restricted (McAlister et al. 1993) although an average loss of 28° of peripheral vision in the inferior meridian occurs even in modern civilian panoramic visor respirators (Samo et al. 2003). The implications for anesthesiologists regarding the remaining restrictions of the visual field have not been investigated in the past. The latest investigations with personal respiratory protection for medical first responders have been carried out by Flaishon et al. (2004a,b) and Vardi et al. (2004), who both used the M15-A1 bi-ocular respirator for their studies. This APR model was designed by Draeger 40 years ago, and is still the standard Israeli Defense Forces APR.

Our study is the first investigation into the specific impact of modern panoramic visor respirators and state-of-the-art bi-ocular military respirators on the anaesthetic management of simulated chemical warfare agent's casualties. We found that neither of the respirators led to a significant delay in treatment. Analyzing the effect sizes we found a minor prolongation of resuscitation tasks when using the bi-ocular respirator. We assume that this might be explained by the bi-ocular frame structure, restricting the visual field of the nasal area. This is confirmed by the results of the questionnaire, in which the anesthesiologists favored the panoramic visor mask due to better visual orientation. In regard to wearing comfort, the participants favored the bi-ocular Draeger M2000 respirator, with a flexible facepiece structure. The volunteers rated the Draeger CDR4500 as more rigid, probably due to the fitted large inflexible polycarbonate visor. However, we agree with King and Frelin that the restriction of the visual field is an important physiological and psychological variable influencing the performance of medical tasks (King and Frelin 1984). Other groups emphasized the usefulness of supraglottic airways like the laryngeal mask under personal protection equipment conditions, especially with the restricted view of a military-type APR and the impaired dexterity due to chemical gloves (Flaishon et al. 2004a).

This study had a number of limitations. Despite the fact that the study was designed to simulate exposure to highly toxic—short latency agents, it was performed under safe and secure conditions without any distressing haste; the participants were not subject to any undue stress and a single patient was being cared for at any one time. Furthermore, the treatment time was limited to perform only the immediate resuscitation measures. In addition, different chemical warfare agents will need a specific therapy besides the standard ALS algorithm (Baker 1999; Karalliedde 1999). In an actual prolonged mass casualty, chemical warfare agents situation, the conditions would clearly be much less favorable (Ben Abraham et al. 2002; Baker 1999). For example, medical caregivers might have to provide emergent support for patients with seizures and copious secretions, vomit and edema overwhelming their upper airways, especially if they had inhaled toxic vapors (Lee 2003; Ben Abraham et al. 2002). Finally, if rescue operations are prolonged, the impact of breathing resistance, peripheral vision, and accumulation of heat will gain more significance.

We conclude that the latest models of personal respiratory protection have only a negligible effect on the immediate anesthetic treatment during well-defined simulated scenarios with a single chemical warfare agent's casualty.

Compared to modern bi-ocular designs, APRs with panoramic visors seem to allow a better orientation for anesthesiologists during airway management and resuscitation.

18.4 Part 2: APR versus PAPRs

The most commonly used respiratory protection devices are APRs where the wearer draws air through a filter (Schumacher et al. 2009; Martyny et al. 2002). The filter canister will remove gases, vapors, and/or aerosols from the inhaled air, depending on the filter capacity and selectivity for various contaminants (WHO 2004). The resulting increase in breathing resistance may have a significant effect on the wearer's ability to function. In recent years, PAPRs have been introduced; these employ a pump which draws ambient air in through a filter and supplies it to the face mask. PAPRs eliminate the problems of heat build-up, dead space ventilation, and airflow resistance (Martyny et al. 2002). On the contrary, their weight, bulk, and the connection to a corrugated breathing tube might immobilize the wearer to a certain extent, especially in confined spaces.

Fourteen UK paramedics carried out a standardized resuscitation algorithm inside an ambulance vehicle, either unprotected or wearing a conventional or a powered respirator.

For respiratory protection, we used the full-face panoramic visor respirator (Promask 40, Scott Health & Safety, Skelmersdale, UK) for both respirator groups. The APR group ($n = 14$) had the 370 g weighing filter canister (CF32 A2B2E2K2-P3, Scott Health & Safety) directly connected to the facepiece (Figure 18.4) and the PAPR group ($n = 14$) had the facepiece connected to the remotely mounted fan and filter unit (Proflow 2SC, Scott Health & Safety) by a corrugated hose (Figure 18.5). For skin protection, we used a CBRN protective overgarment (Saratoga BMI-Suit, Bluecher, Erkrath, Germany) and CBRN protective gloves of medium thickness (Butyl rubber, 0.35 mm, Bluecher, Erkrath, Germany).

Treatment times, wearer mobility, ease of communication, and ease of breathing were determined and compared. In the questionnaire, volunteers stated that communication and mobility were similar in both respirator groups while breathing resistance was significantly lower in the powered respirator group. We found no delay in mean (SD) treatment times between the groups wearing respiratory protection and the controls 245 (19) seconds for controls, 247 (17) seconds for conventional respirators, and 250 (12) seconds for powered respirators (Table 18.3).

Our conclusions from this study were that PAPRs improve the ease of breathing and do not appear to reduce mobility or delay treatment during a simulated resuscitation scenario inside an ambulance vehicle with a single CBRN casualty.

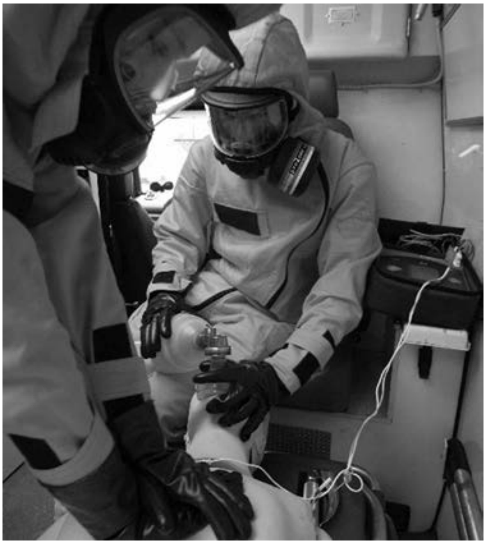

FIGURE 18.4
Air-purifying respirator.

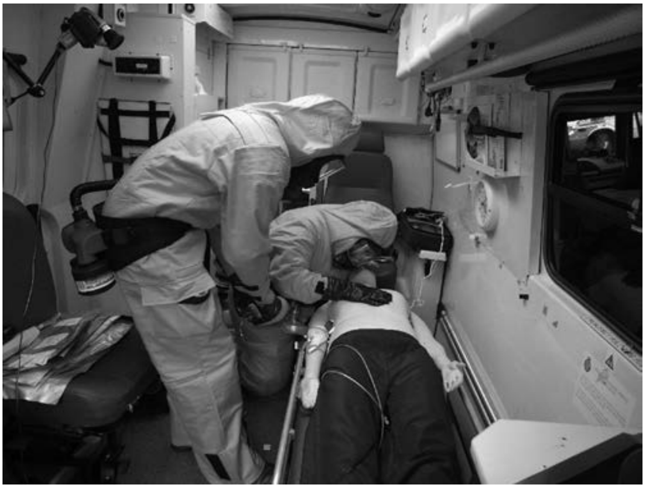

FIGURE 18.5
Powered air-purifying respirator.

18.5 Part 3: Loose-Fitting PAPR Hood versus APR

This was the first CBRN study investigating the influence of respiratory protection equipment on simulated pediatric resuscitation (Schumacher et al. 2013). Children can either be specifically targeted as in the September 2004

TABLE 18.3

Treatment Times of Tasks (seconds, Mean ± SD)

	BVM and Monitoring	ET Intubation and Ventilator	IV Cannulation	IV Drug Application
Control	74 ± 7	69 ± 4	58 ± 6	44 ± 8
APR	73 ± 8	69 ± 7	60 ± 6	45 ± 6
PAPR	75 ± 5	71 ± 6	60 ± 9	44 ± 7

attack on a school in Beslan, Russia, or as in the thwarted attempt to release chlorine gas in Disney World (Cieslak and Henretig 2007), or they can become "collateral damage" as occurred with the deliberate sarin releases in the Tokyo underground in 1995 which affected 16 children and 5 pregnant women (Okumura et al. 1996). Conversely, in during the 1997 accident at a bio-weapons facility in the Soviet city of Sverdlovsk, none of the 66 fatalities had been younger than 24 years (Meselson et al. 1994), because the inadvertent release of anthrax spores occurred during the night, when children are unlikely to be outdoors (Cieslak and Henretig 2003). The aim of this study was to compare APRs and loose-fitting PAPR-hoods on simulated first-response emergency treatment of children suffering from serious transmissible diseases.

Like all previous investigations, the design was a randomized, controlled, crossover study. Sixteen paramedics carried out a standardized emergency pediatric life support (EPLS) scenario inside an ambulance, either unprotected (control) or wearing a conventional APR or a PAPR-hood. Treatment times and wearer comfort were determined and compared.

18.5.1 Personal Protective Equipment

A tight-fitting full-face panoramic visor respirator (CDR4500, Draeger Safety, Hamburg, Germany) was used for the conventional APR group (Figure 18.6). The APR group had a lightweight particulate filter drum (P3 RD40, 35 g, Draeger Safety, Germany) directly connected to the facepiece. The PAPR group had a loose-fitting hood connected to the remotely mounted fan and filter unit (X-plore Long Hood and X-plore 7500, Draeger Safety, Germany, Figure 18.7) by a corrugated hose. The fan/triple-filter unit weighs 1050 g and was mounted on a waist belt (Figure 18.8).

18.5.2 Patient Simulator

The emergency treatment was carried out on a Resusci-Junior Manikin (Laerdal Medical Ltd, Orpington, UK), which has the size and weight of a 5-year-old child. This pediatric patient simulator can be intubated, cannulated, and defibrillated during EPLS exercises (Figure 18.9). All skills were performed using the standard paramedical equipment of the London Ambulance Service NHS Trust at one of their designated training centers.

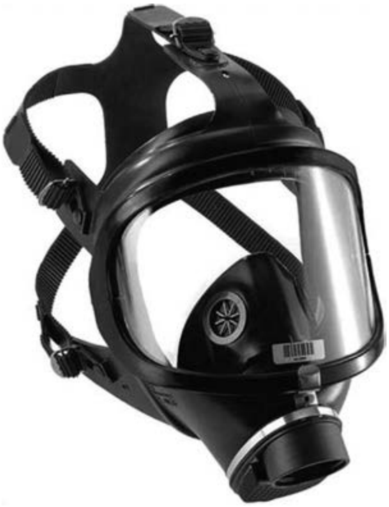

FIGURE 18.6
Tight-fitting full-face mask CDR4500 without P3 Cartridge.

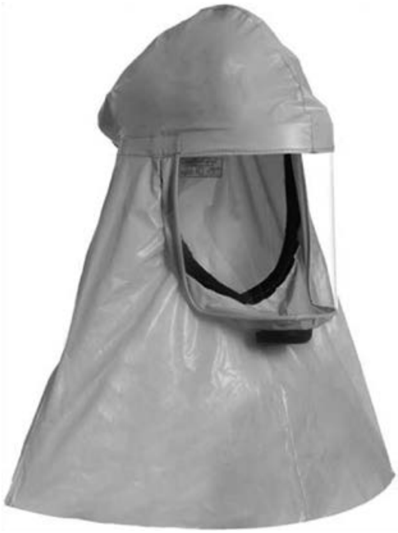

FIGURE 18.7
XPlore long hood.

18.5.3 Study Protocol

The treatment protocol was taken from the standard European Resuscitation Council EPLS algorithm and was strictly compliant with the guidelines and the routine equipment used by the London Ambulance NHS Trust. At the start of the scenario, the medical team approached the simulator manikin.

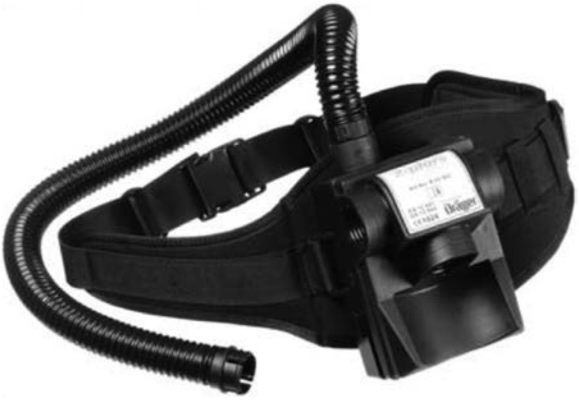

FIGURE 18.8
Belt-mounted blower unit Xplore 7500 without P3 Cartridge.

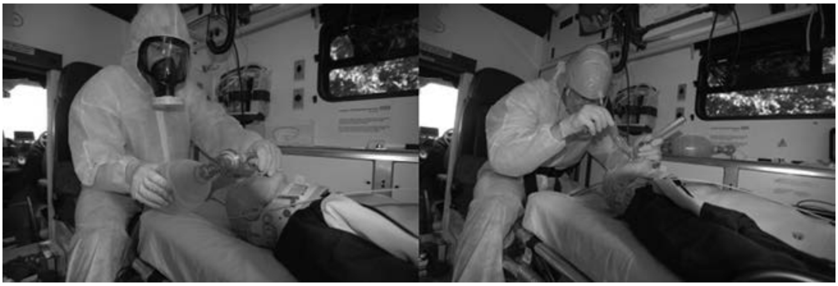

FIGURE 18.9
CDR4500 versus PAPR hood.

After apnea and cardiac arrest were diagnosed, the first task (Task 1) to be accomplished was the successful management of the airway by bag-valve-mask (BVM) ventilation, aided by a Guedel oropharyngeal airway, by one team member. In the meantime, the other paramedic was applying the ECG/Defibrillator (Heartstart FR2, Laerdal Medical Ltd, Orpington, UK). The next task (Task 2) involved readying the endotracheal tube (ID 5.5 mm), pediatric laryngoscope (Macintosh, size 2 blade), and cuff syringe. Following successful intubation of the pediatric manikin's trachea, the tube was secured with a Thomas ETT holder. Task 2 was completed after connection and commencement of manual BVM ventilation. This was immediately followed by Task 3: intraosseous vascular access using the EZ-IO infusion system with a 25 mm needle, followed by injection of a 10 mL bolus of normal saline. Task 4 required identification and preparation of the emergency intravenous drugs and giving atropine and adrenaline, followed by injection of a second 10 mL bolus of normal saline. Throughout the whole procedure (Tasks 1–4), continuous external chest compression was carried out. The time taken to complete each task was recorded. Each paramedic was allocated to all three study arms, whereby the sequence was randomized to counter any learning effects (longitudinal study, randomized crossover design, the order of the sequence was determined by sealed envelopes). Immediately after the treatment module, the participants completed study questionnaire forms in isolation from each other. This was to determine four key qualities of the respirator system: mobility, ease of communication, heat build-up, and dexterity.

18.5.4 Results

All 16 paramedics successfully accomplished the treatment objectives of all study arms without adverse events. The treatment times are displayed in Table 18.4. The overall treatment times were 261 seconds (SD512 seconds) for the controls, 275 seconds (SD59 seconds) for the APR group, and 286 seconds (SD513 seconds) for the PAPR-hood group. Overall treatment times ranged from 244 to 286 seconds for the controls, 259 to 288 seconds for the APR group, and 264 to 318 seconds for the PAPR-hood group. Treatment times for individual tasks are displayed in Figure 18.10. The most time-consuming task carried out was the successful endotracheal intubation (87–92 seconds) and the least time consuming task was the identification and application of the drugs (41–47 seconds). Endotracheal intubation was carried out successfully during all runs. A tracheal tube bougie (angled, 800 mm, 10ch, P3, Bristol, UK) was used by 12 of 16 volunteers. The participating paramedics rated the mobility, ease of communication, and dexterity of the tight-fitting APR system significantly better compared to the loose-fitting PAPR-hood (Table 18.5). Wearer comfort with respect to heat build-up was significantly better in the loose-fitting PAPR-hood group.

TABLE 18.4

Treatment Times of Tasks (Mean ± SD)

	Control (Seconds ± SD) n:16	**APR (Seconds ± SD) n:16**	**PAPR-hood (Seconds ± SD) n:16**	**p**
BVM and Monitoring	73 ± 5	77 ± 4	80 ± 8	0.007
ET Intubation	87 ± 6	90 ± 4	92 ± 4	0.016
IO Cannulation	60 ± 4	63.4 ± 5	67 ± 6	0.001
Drug Application	41 ± 5	44.4 ± 4	47 ± 4	0.074
Total	261 ± 12	275 ± 9	286 ± 13	0.0001

Abbreviations: *BVM*, bag valve mask; *ET*, endotracheal tube; *IO*, intraosseous; *SD*, standard deviation.

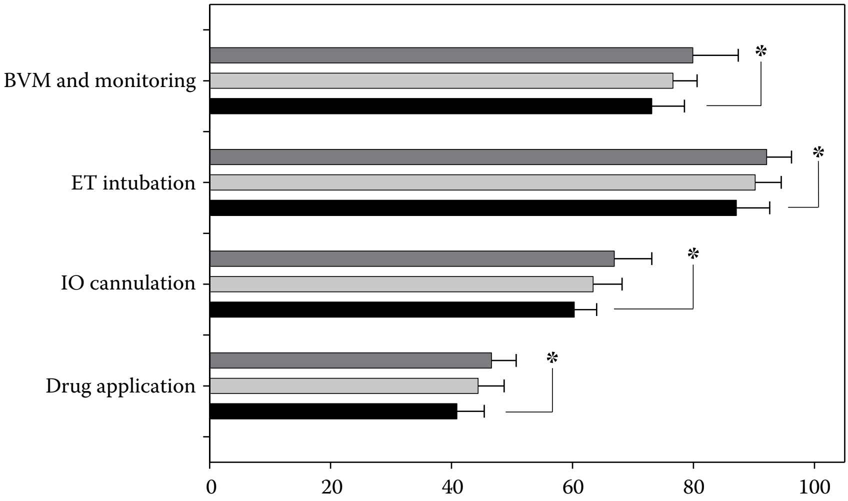

FIGURE 18.10
Treatment times, black bar: control, dark gray bar: PAPR, light gray bar: APR, *$p < 0.05$.

TABLE 18.5
Wearer Comfort Questionnaire (Mean ± SD, n:16)

	APR (Mean ± SD)	PAPR-hood (Mean ± SD)	p-Value
Mobility	2.7 ± 0.5	1.8 ± 0.7	0.000
Noise	3.3 ± 0.7	2.1 ± 0.7	0.001
Heat	1.7 ± 0.7	3.7 ± 0.5	0.000
Dexterity	2.6 ± 0.8	1.8 ± 0.7	0.001

"0" indicating the worst and "5" the best performance.

18.5.5 Discussion

This is the first CBRN study investigating the influence of respiratory protection equipment on simulated pediatric resuscitation. In addition to naturally occurring epidemics (Turner 2011; Scarfone et al. 2011), the threat of mass casualties caused by an intentional release of toxic or pathogenic substances has been highlighted by many governmental and non-governmental health care specialists (White 2002; Sardesai et al. 2002; WHO 2004; Patel et al. 2006; Byers et al. 2008; Baker 2004) The Committee on Environmental Health and Committee on Infectious Diseases states that disaster-response agencies and public health authorities increasingly embrace the concept of an "all-hazards approach" (Committee on Environmental Health 2006). The all-hazards approach is designed to augment public health infrastructure, using an integrated model of disaster response. With this approach, the same protocol created to respond to the appearance of smallpox can easily be modified to contain an outbreak of avian flu. In 2004, there was considerable concern about the spread of the new severe acute respiratory syndrome associated corona virus (SARS-CoV), which provides a good model for the spread of a new infectious pathogen in a world linked by fast air flight connections (Baker 2004). As airborne virulent biological agents, may enter the body via the respiratory system, the majority of serious respiratory infections occur via the inhalational route. During the 2010 H1N1 flu pandemic, the majority of British health care workers were equipped with disposable half mask respirators and visors for splash protection. To ensure an adequate level of personal protection of the attending medical staff, guidelines have been published by the British Department of Health and the Health Protection Agency (UK Department of Health 2012; Health Protection Agency 2012). The most commonly recommended respirator in the health care setting is a N99 respirator, previously called a high-efficiency-particulate-air (HEPA)-filter respirator which is capable of filtering 99.97% of airborne particulates with a median diameter of greater than 0.3 mm (Martyny et al. 2002). The primary limitation of the half-face disposable respirator is the anatomical fit. Because of leakage, they may not provide the protection necessary for situations involving high levels of exposure or immediately life-threatening pathogens (Martyny et al. 2002; Howie 2005). In addition to the genuinely limited face seal, half-mask respirators need to be combined with goggles or a face shield for eye protection. Goggles and face shields have the disadvantage of fogging, especially during longer operation times. If the wearer is exposed to immediately life-threatening pathogens or toxic chemicals, full-face respirators with a genuinely better seal are recommended (Martyny et al. 2002). They are available as tight-fitting negative pressure masks, known as APRs, with the wearer drawing air through a filter. The other advantage over the combination of a half mask and goggles is the genuine airflow management of modern full-face respirators: The filtered inspiratory airstream is directed across the visor to prevent fogging, and then enters an oronasal inner mask inside the main face mask. The inner mask seals the oronasal space from the eye space, and an expiratory valve ensures that the humid warm exhaled air leaves the inner mask directly into the atmosphere (Wetherell and Mathers 2007). The breathing resistance of the filter depends on the type and amount of the adsorption media, and the type and surface area of the microfiber paper. Modern APRs only exert a resistance of 1–2 mbar; however this can substantially increase the work of breathing by increasing the resistance to both inspiratory and expiratory airflow, and by increasing dead-space ventilation. The increase in inspiratory resistance is the dominant physiological effect (Louhevaara 1984; Harber et al. 1989). To counteract these burdens, PAPRs have been developed that employ a pump which continuously draws ambient air in through a filter and supplies it to the loose-fitting hood. The constant airstream is directed across the visor to prevent fogging. The fan and filters may be carried by the user; with some units the air is fed to the user via tubing with the fan and filters unit remotely mounted. Although they are more expensive, PAPRs eliminate the problems of heat build-up, dead-space ventilation, and airflow resistance (Martyny et al. 2002). Loose-fitting PAPR-hoods can be worn by people with facial hair and seem to be tolerated for longer periods, all this possibly resulting in better compliance with respirator use. On the contrary, their weight, bulk, and the connection to a breathing tube might immobilize the wearer to a certain extent, especially during delicate medical tasks in confined spaces such as an ambulance vehicle. In this study, it was found that the PAPR-hood, but not the tight-fitting APR, led to a significant delay in treatment compared to the controls. The authors assume that the bulky, loose-fitting hood and its rigid connection by a corrugated hose to the belt-mounted fan unit led to a more cautious and protective operation, which prolonged the treatment times. The tight-fitting APR ensemble was evaluated as more reassuring and less cumbersome by the majority of volunteers. This might have been an encouragement to gather momentum during the scenario, even in the limited space provided by an ambulance. This explanation might also be supported by the findings of a previous investigation during adult ALS. By using a tight-fitting face mask in one group as an APR, in the other as a PAPR, the participants felt equally safe and confident during the tasks (Schumacher et al. 2009). The results of this study are inconsistent with a survey of health care workers who had used the loose-fitting hood PAPR in clinical practice during the SARS-CoV outbreak in Singapore, when use of a PAPR was mandatory and widespread (Khoo et al. 2005). Only a minority of respondents found the PAPR uncomfortable, despite some interference with communication. Despite its much higher cost, the majority (84%) preferred to use the PAPR rather than the N-95 respirator when treating suspected SARS-CoV patients. However, the survey was undertaken within the adult Intensive Therapy Unit/High Dependency Unit (ITU/HDU) setting, whereas the subjects in this study were operating in the prehospital setting inside an ambulance. In 2007, Greenland et al. examined the impact of three types of personal protection equipment on the ability of anesthesiologists to intubate manikins using four different intubation techniques (Greenland et al. 2007). While focusing on the skill of tracheal intubation, they found no delay in their PAPR-hood group. This might be explained by the multiple tasks including CPR and intraosseous access volunteers in the present study had to perform within the limited space of the ambulance and the pediatric airway paramedics had to manage. In regard to the feasibility of intraosseous access, the results of this study are comparable to the recent publication of Lamhaut in which the superiority of intraosseous compared to intravenous access in adults under CBRN conditions was investigated (Lamhaut et al. 2010).

18.5.6 Conclusions

This study showed that when using lightweight particulate filters, conventional tight-fitting APRs are preferable to loose-fitting PAPR-hood ensembles during simulated EPLS in the limited space of an ambulance. Despite their cooling, air-conditioning qualities, PAPR-hoods were rated less favorably with respect to mobility, communication, and dexterity during pediatric cardiopulmonary resuscitation.

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19

Respiratory Protection for Emergency Responders

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19.1 History of National Institute for Occupational Safety and Health Respiratory Protection Approval for First Responders

The National Institute for Occupational Safety and Health (NIOSH) is a federally mandated agency responsible for conducting research and making recommendations for the prevention of work-related injury and illness. NIOSH houses the Respirator Approval Program (originating in the U.S. Bureau of Mines). The program's key functions include developing and implementing performance standards for respirators used in an occupational setting in accordance with Title 42 Code of Federal Regulations Part 84 (42 CFR 84) and certifying respirators that meet performance standards (herein referred to as "NIOSH-approved") (Department of Health and Human Services, 1995). This authority is derived from the federal Occupational Safety and Health Act of 1970 and the Mine Safety and Health Act of 1977. The Occupational Safety and Health Administration (OSHA) regulates occupational safety and health in private sector workplaces. Since 1970, OSHA has required that civilian respirators be NIOSH-approved for occupational use (Occupational Safety and Health Administration, 2011).

Emergency responders, consensus standards associations, and the U.S. federal government play critical roles in collaborating to identify next-generation needs. These groups also define personal protective technology and equipment standards that help protect workers against perceived and known threats that include chemical, biological, radiological, and nuclear (CBRN) terrorism agents. An example of this collaborative relationship is the one between NIOSH and the National Fire Protection Association (NFPA). NIOSH and the NFPA forged an alliance 10 years ago to conduct important research on firefighter health and safety. The first NFPA document to address firefighter respiratory protection was NFPA number 19B, *Standard on Respiratory Protective Equipment for Fire Fighters,* 1971. This standard prohibited the use of air-purifying canister filtration media in masks for firefighters and permitted the first time use of self-contained breathing apparatus respirators (SCBAs) (National Fire Protection Agency, 1971). In 1974, NIOSH and the U.S. Bureau of Mines issued the first open circuit, pressure-demand SCBA approval in accordance with the requirements of 30 CFR Part 11. The first open circuit, demand SCBA approval was issued in October 1973. Demand SCBAs allow the air to flow into the facepiece only on "demand" by the wearer (i.e., demand SCBA or negative-pressure SCBA). Pressure-demand SCBAs have a pressure-demand valve that is held slightly open allowing a continual air flow into the facepiece to maintain positive pressure (Bollinger and Schutz, 1987). The NFPA 19B standard was replaced in 1981 by the consensus standard, *Standard on Self-Contained Breathing Apparatus for Fire Fighters.* This standard specifies that NFPA SCBAs be approved by NIOSH and the Mine Safety and Health

Administration (MSHA), have a minimum rated service life of 30 minutes, and requires all fire service open-circuit SCBAs to be positive pressure (National Fire Protection Association, 2007). The NFPA 1981 standard—updated and republished every five years—was the first public standard that advocated the NIOSH-approved CBRN protection requirement for fire service SCBAs. NIOSH continues to issue SCBA approvals for the mining industry (jointly with MSHA) as well as non-mining, non-CBRN, and CBRN SCBA approvals under 42 CFR Part 84 and in accordance with the CBRN SCBA standard.

19.2 Need for CBRN Respiratory Protection

In addition to occupational use, emergency responders are required to use NIOSH-approved respirators for expected hazards (Occupational Safety and Health Administration, 2004, 2009a, b). Prior to 2001, there were no U.S. standards for emergency response personnel using respiratory protective devices (RPDs) for expected CBRN terrorist threats (e.g., chemical, biological). Neither industrial nor military respirators provided protection from all potential CBRN respiratory hazards; therefore, standards were needed to protect responders against CBRN threats. In 1999, NIOSH, the Department of Defense (DOD), and OSHA sponsored a Chemical and Biological Respiratory Protection Workshop to explore potential hazards, respiratory protection needs, RPD standards, and public health and medical community concerns associated with chemical and biological terrorism. This workshop marked the beginning of NIOSH standards development activities to add CBRN protection to several respirator classes. Attendees expressed the need for NIOSH-approved respirators that provide adequate protection against chemicals potentially released in a terrorist attack (National Institute for Occupational Safety and Health, 2000). Attendees revealed both chemical warfare agents (CWAs) and toxic industrial chemicals (TICs) were of concern to first responders. Guidelines and standards were needed to assess chemical and/or biological concentration levels of response scenarios.

In addition, the certification of respirators for use against these threats was noted as a requirement. Respiratory protection standards and certifications for SCBAs, air-purifying respirators (APRs), and powered air-purifying respirators (PAPRs) were listed as immediate responder needs. NIOSH was urged to provide leadership to bring appropriate military, safety, and health experts together to develop the necessary standards and protect the nation's emergency responders. Several federal agencies collaborated to address gaps in knowledge, technology, standards, and training. Agencies involved included the Department of Justice (DOJ), Office of Justice Programs, Office of Domestic Preparedness, Department of Commerce, National Institute of Standards and Technology (NIST), DOD, Department of Labor, OSHA, International Association of Fire Chiefs, International Association of Fire Fighters, International Safety Equipment Association, Memorial Institute for the Prevention of Terrorism, and NFPA.

Before NIOSH could develop performance standards to protect against CBRN respiratory hazards, various agents that have the potential to be used in acts of terrorism needed to be identified. The toxicity and chemical/physical properties of identified CBRN agents were essential for NIOSH to further identify test challenge agents, their chemical concentrations to challenge the CBRN respiratory equipment, and breakthrough concentrations for development of performance standards. In collaboration with other federal agencies, NIOSH developed national CBRN respirator certification standards to evaluate candidate respirators designed to protect fire service, law enforcement, and other public safety emergency response personnel from the effects of CBRN agents.

19.3 Description of CBRN Respiratory Hazards

19.3.1 CBRN Threat Assessment

The NIOSH, DOD, and NIST evaluation of potential CBRN and TIC hazards, as well as the NIOSH evaluation of the materials constructing the respirator, indicated that the characteristics of the respirator (including facepiece-to-user interfaces) needed to be verified and evaluated for each commercially available respirator that was submitted for NIOSH certification. The interagency members also recognized that the research priority would be the toxic chemical agents because toxic chemical agent gases and vapors were known to have greater permeation and penetration characteristics through facepiece material than radiological or biological particulates. The interagency members concluded the chemical agent challenge concentration and each agent's unique permeation and penetration effects on respirator samples must be determined.

The selection of test agents to challenge CBRN RPDs was based on a comprehensive review of available technical data and through consultations with various government agencies (e.g., DOD, DOJ, Department of Energy, Environmental Protection Agency (EPA), Agency for Toxic Substances and Disease Registry, NFPA 1994 standard, U.S. Army Center for Health Promotion and Preventative Medicine [USACHPPM] Technical Guide 244, and other classified sources). A total of 151 toxic industrial TICs/CWAs were identified as potential candidates for challenge agents. NIOSH and the U.S. Army Soldier and Biological Chemical Command (SBCCOM) evaluated the candidate agents based on various characteristics, including physical properties and interaction with activated carbon (e.g., for permeation [molecularly diffusing through material] and penetration [seeping through interfacing components]).

19.3.2 Chemical Threats

NIOSH held a public meeting in 2001 to discuss the development of CBRN standards (CBRN Standards Public Meeting, 2001). One of the recommendations was to use the CWA challenge chemicals identified in the NFPA 1994 standard as part of the NIOSH standard. NFPA 1994 is a standard to determine the permeation of CBRN agents into chemical personal protective clothing (NFPA, 2012). The NFPA Technical Committee provided recommendations and rationale for the selection of nine chemicals, which included four CWAs. The CWAs identified in NFPA 1994 were HD (or distilled mustard), Lewisite ("L"), Sarin (or GB), and VX as well as permeation resistance to liquid TICs (dimethyl sulfate [DMS]) and gaseous TICs (ammonia, chlorine, hydrogen cyanide, and cyanogen chloride).

19.3.2.1 Chemical Penetration/Permeation Test

NIOSH evaluated the physical characteristics of the CWAs listed in USACHPPM TG 244, the 151 CWAs/TICs identified as part of the NIOSH/SBCCOM review, and the CWAs/TICs listed in NFPA 1994 standard to select representative test agents for chemical penetration/permeation tests. Many of the TICs identified as part of the 151 materials did not have well-defined chemical characteristics or physical properties. When considering the effects of these agents on respirators and the likelihood of use in a terrorist incident, GB and HD best represented the list of potential agents and were selected for the penetration/permeation test due to the chemicals' physical properties and molecular structure. However, it is important to note that this is not a stagnant analysis—as physical data is incorporated into the TICs list, additional chemicals may be identified that could be added to the test procedure. Future developments in the form of new agents, methods of deployment and dissemination, and availability require constant overview to ensure certification testing matches the identified threats. At the time of the standard development, both GB and HD were considered to be reasonable challenge agents given their permeation and penetration characteristics, relative ease to produce, and worldwide availability in thousands of metric tons. The GB and HD CWA challenge concentration requirements were derived by averaging multiple indoor concentration–time profiles from the most likely dispersal scenarios.

NIOSH with consultation with SBCCOM selected GB as the representative for nerve agents because it is the most volatile of the nerve agents, having a volatility of 22,000 mg/m^3 (National Institute for Occupational Safety and Health, 2011a). The low molecular weight and molecular structure of GB enables the permeation through respirator materials more readily than other G-series (e.g., soman) and V-series agents (e.g., VX). A liquid GB test is not performed since GB is so volatile—the liquid would evaporate shortly after the test started. Therefore, GB vapor adsorbed on the surface of the respirator was the only challenge source for permeation.

NIOSH and SBCCOM also selected HD as a test agent because of its permeation characteristics. HD is a linear molecule (as compared with GB which has a branched configuration), and is expected to permeate most materials at a faster rate than GB. Thus, HD was a choice agent to evaluate permeation through the respirator facepiece material. A combination liquid–vapor test was used for the HD tests, where liquid droplets of HD were placed on selected areas of the respirator and a vapor challenge of HD was introduced into the test chamber. Liquid HD tested the permeation, but also indicated if the integrity of the respirator polymeric materials were able to withstand the persistent chemical effects of HD. Adding a vapor challenge to the chamber tested for penetration leaks. Other CWAs and TICs, including VX, Lewisite, hydrogen cyanide, phosgene, chlorine, DMS, and ammonia, were not selected mainly due to their low volatility and large molecular size (which cause low permeation).

19.3.2.2 Air-Purifying Filtration Performance

A list of chemicals, biological agents, and radiological agents identified in the original hazard assessment that should be considered in developing standard requirements were outlined in the presentation, "*CBRN Canister Requirements*" delivered at the 2003 NIOSH public meeting (National Institute for Occupational Safety and Health, 2003). In an effort to reduce the number of certification tests necessary as part of a CBRN APR standard, NIOSH and SBCCOM categorized the potential respiratory hazards into chemical classes and selected test representative agent(s) (TRAs) for each class based on the interaction with the cartridge/canister sorbent. The gas filter component (i.e., sorbent) of canisters and cartridges generally consists of activated carbon where challenge agents are primarily removed through physical adsorption to the carbon. Often, the activated carbon is impregnated with chemicals that assist in removing the challenge agents through chemical reaction. Other materials, such as synthetic polymers and zeolite, have been tested for filtration, but no other sorbent has proven to be as widely applicable as activated carbon.

A NIOSH-approved CBRN APR canister provides protection against a minimum of 139 identified CBRN agents, which are classified into the following seven families: organic vapors (61), acid gases (32), base gases (4), hydrides (4), nitrogen oxides (5), particulates (32) (composed of three chemical, 13 biological, and 16 radiological and nuclear particulate threats), and formaldehyde (1). The TRAs NIOSH uses for certification testing to represent each agent family are listed in Table 19.1.

There is a diverse ability for chemicals within the organic vapor/hydrocarbon class to be adsorbed into activated carbon. Therefore, a method defining the relative adsorption affinity of carbon for particular agents was devised. A number of physical properties were considered, including molecular weight, boiling point, vapor pressure, relative toxicity, and polar/

TABLE 19.1

CBRN APR Canister Terrorist Threat Protections

Acid Gas Family (32 agents)

5-TRA chemicals are used for NIOSH certification testing to represent the Acid Gas Family

They are cyanogen chloride, hydrogen cyanide, hydrogen sulfide, phosgene, and sulfur dioxide

- Boron tribromide
- Boron trichloride
- Boron trifluoride
- Bromine
- Bromine chloride
- Bromine trifluoride
- Carbonyl fluoride
- Chlorine
- Chlorine pentafluoride
- Chlorine trifluoride
- Chlorosulfonic acid
- Cyanogen chloride (CK)
- Dichlorosilane
- Ethyl phosphonous dichloride
- Fluorine
- Hydrogen bromide
- Hydrogen chloride
- Hydrogen cyanide (AC)
- Hydrogen fluoride
- Hydrogen iodide
- Hydrogen sulfide
- Phosgene (CG)
- Phosphorus trichloride
- Silicon tetrafluoride
- Sulfur dioxide
- Sulfur trioxide
- Sulfuric acid
- Sulfuryl chloride
- Titanium tetrachloride
- Tungsten hexafluoride
- Bromine pentafluoride
- Hydrogen selenide

Nitrogen Oxide Family (5 Agents)

1 TRA chemical (nitrogen dioxide) is used for NIOSH certification testing to represent the nitrogen oxide family

- Nitric acid
- Nitric acid, fuming
- Nitrogen dioxide
- Nitrogen tetraoxide
- Nitrogen trioxide

Base Gas Family (4 Agents)

1 TRA chemical (ammonia) is used for NIOSH certification testing to represent the base gas family

- Allyl amine
- Ammonia
- Dimethyl hydrazine, 1,2
- Methyl hydrazine

Hydride Family (4 Agents)

1 TRA chemical (phosphine) is used for certification testing to represent the hydride family

- Arsine
- Germane
- Phosphine
- Stibine

Formaldehyde Family (1 Agent)

1 TRA chemical (formaldehyde) is used for certification testing to represent the formaldehyde family

- Formaldehyde

(*Continued*)

TABLE 19.1 ***(Continued)***

CBRN APR Canister Terrorist Threat Protections

Organic Vapor Family (61 Agents)
1 TRA chemical (cyclohexane) is used for certification testing to represent the organic vapor family

NOTE: CWAs are in this TRA OV family

Acetone cyanohydrin
Acrylonitrile
Allyl alcohol
Allyl chlorocarbonate
Bromoacetone
Bromobenzylcyanide (CA)
Chloroacetone
Chloroacetonitrile
Chloroacetophenone (CN)
Chloroacetyl chloride
Chloropicrin (PS)
Chloropivaloyl chloride
Crotonaldehyde
Cyclohexyl methyphosphonate
Dibenz-(b,f)-1,4-oxazepine (CR)
Diketene
Dimethyl sulfate
Diphenylchloroarsine
Diphenylcyanoarsine
Diphosgene (DP)
Distilled mustard (HD)
Ethyl chloroformate
Ethyl chlorothioformate
Ethyl phosphonothioicdichloride
Ethyl phosphorodichloridate
Ethylene dibromide
Hexachlorocyclopentadiene
Hexaethyl tetraphosphate
Iso-butyl chloroformate
Iso-propyl chloroformate
Lewisite (L, L-1, L-2, L-3)

Methanesulfonyl chloride
Methyl orthosilicate
Methyl parathion
Methyl phosphonic dichloride
Mustard, lewisite mixture
Nitrogen mustard HN-1
Nitrogen mustard HN-2
Nitrogen mustard HN-3
N-propyl chloroformate
O-chlorobenzylidene malononitrile (CS)
O-ethyl-s-(2isopropyaminoethyl)methyl phosphonthiolate
Parathion
Perchloromethyl mercaptan
Phenyl mercapatan
Phenylcarbylamine chloride
Phenyldichloroarsine
Phosgene oximedichloroforoxime
Phosphorus oxychloride
Sarin (GB)
Sec-butyl chloroformate
Soman (GD)
Tabun (GA)
Tert-octyl mercapatan
Tetraethyl dithiopyrophosphate
Tetraethyl lead
Tetramethyl lead
Tetranitromethane
Trimethoxysilane
Trimethylacetyl chloride
VX

Particulate Family Canister Protections (32 Agents)
1-TRA chemical (dioctyl phthalate [DOP]) is used for certification testing to represent the particulate family.

Particulate—Chemicals (3)

Sodium azide
Adamsite
Sodium fluoroacetate

(*Continued*)

TABLE 19.1 ***(Continued)***

CBRN APR Canister Terrorist Threat Protections

Particulate—Biological (13)	
Anthrax	Venezuelan equine encephalitis
Glanders	Brucellosis
Tularemia	Pneumonic plague
Smallpox	Query (Q) fever
T-2 Mycotoxins	Viral hemorrhagic fevers
Ricin	Botulism
Staphylococcus enterotoxin B	
Particulate—Radiological/Nuclear (16)	
Carbon 14	Hydrogen 3
Cobalt 60	Phosphorous 32
Strontium 90	Nickel 63
Iodine 131	Technetium 99 m
Promethium 147	Cesium 137
Radium 226	Thallium 204
Uranium 235 and 238	Thorium 232
Americium 241	Plutonium 239

nonpolar characteristics. During the standards development process, the best indicator of the ability to be adsorbed on activated carbon was vapor pressure. Chemicals with a lower vapor pressure have greater affinity for activated carbon. Cyclohexane was chosen to be the representative chemical for organic vapors. Cyclohexane has been accepted as an organic vapor TRA by other standard generating organizations, including the Europeans and the Japanese (Furuse et al., 2001; HSE, 2013). A canister or cartridge that passes the organic vapor test provides protection for all organic vapors having vapor pressures less than that of cyclohexane. Sixty-one organic chemicals from the CWAs/TICs are covered by this.

19.3.3 Biological Threats

NIOSH considered 13 high-threat biological agents when developing the standards which were either identified in the Centers for Disease Control and Prevention (CDC) list of biological threat agents or from the U.S. Army Medical Research Institute of Infectious Diseases (USAMRID) list. The following NIOSH list consisting of bacterial agents, viral agents, and toxins was adapted from those sources and are currently still considered high-threat biological agents: anthrax, brucellosis, glanders, pneumonic plague, tularemia, Q fever, Venezuelan equine encephalitis, viral hemorrhagic fevers, T-2 mycotoxins, botulism, ricin, *Staphylococcus*, enterotoxin B, and smallpox. NIOSH concluded these identified biological agents are either a particulate or vapor droplet hazard; thus if NIOSH-approved CBRN respirators could provide a minimum level of respiratory protection against a chemical particulate, aerosol, vapor, or gas, the respirators would provide minimal protection against particulate or aerosol biological agents. Figure 19.1 is an illustration of the filter efficiency of high efficiency particulate air (HEPA) and P-100 filters demonstrating various particle sizes and the size range of common biological agents.

19.3.4 Radiological/Nuclear Threats

Another task of the hazard assessment was to determine the most likely radiological particulate agents to be encountered in a domestic radiological particulate or nuclear detonation terrorist act. The 16 radiological/nuclear agents considered when developing the NIOSH CBRN respirator standards were: hydrogen-3, carbon-14, phosphorous-32, cobalt-60, nickel-63, strontium-90, technetium-99m, iodine-131, cesium-137, promethium-147, thallium-204, radium-226, thorium-232, uranium-235 and 238, plutonium-239, and americium-241. Dispersion of radiological agents can produce an internal or external radiological hazard or both at the scene of a terrorist attack. External radiation exposure is defined as the dose equivalent received from radiation sources outside the body. Alpha radiation is not normally regarded as an external radiation hazard because it cannot penetrate the outer layers of the skin. The external radiation hazard may be due to beta, gamma, or neutron sources, all of which can penetrate the sensitive organs of the body. Figure 19.2 illustrates the penetration potential for alpha, beta, gamma, or neutron radiation.

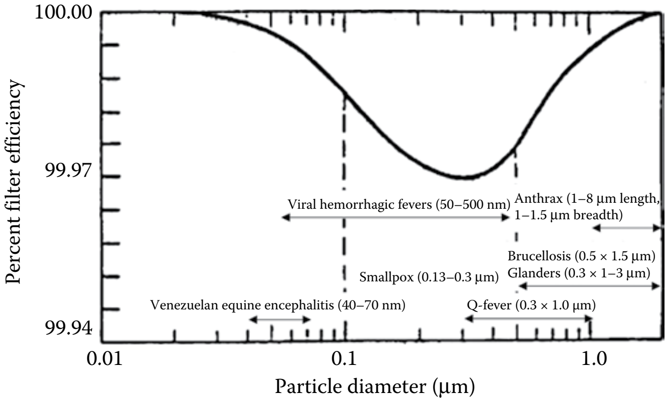


FIGURE 19.1
Illustration of the filter efficiency science of HEPA/P-100 Filters for the various particle diameter sizes with emphasis on the size of the most penetrating particle, and the size range of common biological agents. (Courtesy of HEPA/P-100 Filters for Biologicals; Presentation NBC Hazards-Implications for respiratory protection by Scott Deitchman and Frank Palya; Joint NIST/NIOSH/SBCCOM Stakeholder Meeting, April 17–18, 2001, Richland Ball Room, Edgewood, MD.)

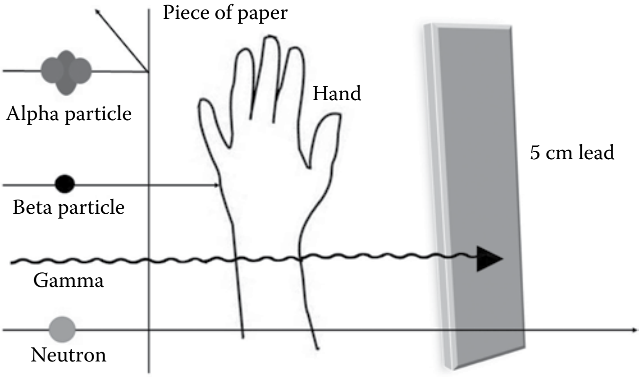


FIGURE 19.2
Illustration of the penetration potential of alpha and beta particles, a gamma ray, and a neutron emitted from an external radiation source. (Courtesy of Radiation Penetration from an External Source; Adapted from Presentation NBC Hazards-Implications for respiratory protection by Scott Deitchman and Frank Palya; Joint NIST/NIOSH/SBCCOM Stakeholder Meeting, April 17–18, 2001, Richland Ball Room, Edgewood, MD.)

Internal radiation exposure is the dose equivalent received from radioactive material taken into the body by ingestion, contamination of wounds, or inhalation (U.S. Nuclear Regulatory Commission, 1995). Full facepiece, tight-fitting respirators cannot provide the wearer protection against external radiation exposure. However, when worn and used correctly, these respirators can provide a minimum level of protection against internal radiation exposure by capturing radioactive particles on a P-100 filter bed and reduce contact with the dermal surfaces of the face by the full facepiece (Department of Energy, 2008). NIOSH used the same approach to protect against radiological particles as it did for biological agents. If a NIOSH-approved CBRN respirator could provide protection against a chemical particulate, aerosol, vapor, or gas, it would provide protection against radiological particulates or nuclear detonation radioactive particulate fallout. NIOSH requires that CBRN non-powered APRs meet filtration performance requirements of a P-100 filter to provide a minimum known level of protection against particulate material contaminated with radioactive material.

19.3.5 Additional Standards Considerations

19.3.5.1 Tiers of Requirements

Based upon the review of threats and standards, the CBRN interagency group determined that numerous performance requirements addressing breathing flow rates, flame and heat resistance, rough handling, communications, vision, and other human factors including facepiece fit were essential to ensuring that CBRN respirators would safely protect users. In addition to the tests that evaluate penetration and permeation resistance, and performance in gas and vapor chemical and particulate testing, NIOSH incorporated requirements from national and international consensus standards as part of the CBRN respirator performance requirements (National Personal Protective Technology Laboratory, 2016a).

19.3.5.2 Laboratory Respirator Protection Level

A major concern for development of the NIOSH CBRN respirator standards was the potential exposure of CBRN agents through the respirator–human interface that may be due to an inadequate face seal or a poorly fitted respirator. Also, the respirators needed to be able to fit a wide range of the population. NIOSH addressed the facepiece fit concern by adding a new quantitative fit test method identified as the Laboratory Respiratory Protection Level (LRPL). The LRPL test is required in all NIOSH CBRN respirator standards and assesses how well the respirator facepiece fits to a wearer's face through a series of 11 standard exercises (National Personal Protective Technology Laboratory (NPPTL), 2008). 42 CFR Part 84 and NIOSH CBRN SCBA respirator Statement of Standard requires evaluation of the entire individual respirator assemblies configured in the most accessorized configuration or in a special configuration, as determined by NIOSH (National Institute for Occupational Safety and Health, 2011b), However, it is still necessary for the employer to develop—and the respirator wearer to follow—a written respiratory protection program in accordance with OSHA regulations to ensure a conformity assessment and validation of the intended CBRN respirator design and its capacity to minimize or eliminate the total amount of interface inward leakage.

19.4 Development of the CBRN Respiratory Conformity Assessment Process

19.4.1 CBRN SCBA Respirator Standards

Prior to September 11, 2001 (9/11), NIOSH standards and NFPA consensus standards addressed certain requirements that were unique to residential, industrial, or structural firefighting and rescue operations regarding SCBAs as complete systems. SCBAs were not evaluated under laboratory conditions against any form of TICs, or special CWAs. NIOSH and its federal partners created interagency agreements and looked for scientific and engineering information that could help protect against the penetration and permeation of CWAs that had the potential to contaminate air pressure boundaries and degrade materials of the SCBA. After the 9/11 terrorist attacks, the occupational safety and health needs of civilian emergency responders became a top priority for NIOSH, OSHA, and the DOD. The NIOSH CBRN SCBA standards development process consisted of nine phases. This process was also adopted as a standards development template for the creation of the subsequent air-purifying and escape respirator standards offering CBRN protection (National Institute for Occupational Safety and Health, 2010a,b). The nine steps of the process from 2001 to 2003 are as follows:

1. Identify threats and conduct hazard analysis
2. Determine needed protections, dosage, and system test values
3. Conduct literature search to include environmental and durability conditioning standards and human factors requirements
4. Benchmark and formulate laboratory test requirements, procedures, and equipment resources for each test plan
5. Write and publish standards concept paper
6. Write, validate, and verify standard test procedure
7. Adopt applicable quality assurance provisions
8. Conduct public meetings for vetting the draft and final standard. Reconcile public comment. Generate administrative application procedures and specific CBRN caution and limitation statements to support certification functions
9. Implement by policy, via published NIOSH Letters to All Manufacturers

The NIOSH standards development and respirator certification programs led to an increase in the national inventory of CBRN protection for emergency response personnel (National Personal Protective Technology Laboratory, 2016b). In 2002, and in conjunction with the NFPA, new approval applications requesting CBRN protection were processed by NIOSH in three tiers: the first tier was 42 CFR 84 evaluation, the second tier was NFPA 1981 evaluation, and the third tier was special NIOSH CBRN live agent testing and corn-oil LRPL fit evaluation. Each evaluated configuration consists of an extensive quantity of part-numbered subcomponent assemblies that are produced by the manufacturer and assembled into a complete respirator. All the required subcomponent parts for a complete respirator are listed on the respirator manufacturer's assembly matrix. Components and materials of a NIOSH-approved CBRN SCBA and other NIOSH-approved SCBAs are different and must not be intermixed. Only components with exact part numbers shown on the full NIOSH CBRN SCBA approval label are considered a subcomponent of a fully assembled CBRN respirator approval (National Institute for Occupational Safety and Health, 2011a,b,c). More information regarding the CBRN SCBA can be found on the NIOSH Fact Sheet (National Institute for Occupational Safety and Health (NIOSH), 2011c).

From 2001 to 2006, emergency responders operated in the field with a mixture of CBRN and industrial approved SCBAs. To address the SCBAs already deployed in the field, NIOSH introduced retrofit kits to upgrade the devices to NIOSH CBRN protections. NIOSH still issues approvals that allow the retrofit of field-deployed NFPA non-CBRN SCBAs to be upgraded to NFPA-compliant NIOSH-approved CBRN SCBA. The 2007 edition of the 1981 standard informs the fire service community that NIOSH CBRN protection offers levels of protection that did not exist prior to the creation of the NIOSH CBRN SCBA standard. NFPA 1981–2007 edition, further clarifies this perspective and reads:

> CBRN certification offers verification of enhanced protection for emergency responders that is not otherwise available. Without (NIOSH) CBRN protection, SCBA subcomponents are not tested for permeation, penetration, corrosion resistance, or other detrimental effects from exposure to toxic industrial chemicals during hazardous materials incidents and hazardous chemical warfare atmospheres. NIOSH benchmark testing of non-CBRN hardened SCBA against CBRN agents demonstrated that chemical warfare agents (CWAs) could cause catastrophic failures within minutes of exposure (National Fire Protection Association, 2007).

19.4.2 APR and Air-Purifying Escape Respirator

In 2003, NIOSH implemented a voluntary program to accept applications to test and evaluate full-facepiece APRs and air-purifying escape respirators (APERs) for use against CBRN agents. These respirators are tested to ensure protection against specified levels of CBRN agents. Care must be taken to identify the components of an APR with CBRN protection because the NIOSH approval label issued with the respirator may contain both CBRN APR gas mask and non-CBRN APR gas mask subcomponents. The respiratory protection program administrator should ensure the CBRN APR is assembled with the correct components for the required protection in accordance with the manufacturer's user instructions and NIOSH CBRN labels. Industrial APR canisters are not tested against CWAs; the components of industrial APR and CBRN APR are not interchangeable. Some NIOSH-approved CBRN APRs require special subcomponents to be in place for the respirator to provide rated NIOSH CBRN protection (National Institute for Occupational Safety and Health, 2013).

NIOSH CBRN APRs have unique performance, use limitations, and storage requirements specific to CBRN APRs and not NIOSH-approved industrial APRs. NIOSH CBRN APRs are not evaluated at the same toxic agent concentration levels as CBRN SCBAs. Therefore, CBRN APRs are not to be used as entry devices into unknown or potential CBRN agent atmospheres. The respirators are intended to be used by emergency responders that are enrolled in a written respiratory protection program that establishes change-out schedules and performs hazard analysis and concentration characterization steps in the respirator selection process. Because of the single-canister requirement, NIOSH CBRN APRs are frequently not assigned for use in military activities by active or reserve military personnel which may require military-specified gas masks or other unique military designs. NIOSH CBRN APRs can be specified for use by U.S. government civilian military workers in accordance with written installation respiratory protection program requirements and within the scope of the NIOSH approval. Approved CBRN APRs may only be used to escape an immediately dangerous to life or health (IDLH) atmosphere, and are not to be used in oxygen-deficient atmospheres or used to enter any IDLH atmosphere. More information on NIOSH-approved CBRN APR can be found on the NIOSH Fact Sheet (National Institute for Occupational Safety and Health, 2016a).

19.4.3 Powered Air-Purifying Respirators

PAPRs are generally connected to a tight-fitting full facepiece via a breathing hose which is connected to a blower device affixed with canisters and mounted on a waist belt, back pack, or single hose-canister device mounted directly to the facepiece. In 2006, NIOSH issued the CBRN PAPR standard addressing tight-fitting and loose-fitting PAPRs. NIOSH-approved CBRN APRs, APERs, and PAPRs are subjected to environmental and durability conditioning procedures while the test samples are stored in manufacturer-specified minimum packaging configurations (MPCs). MPCs are the protective packaging in which the end user must store or maintain the CBRN air-purifying device and its required components. The manufacturer's user instructions and the full NIOSH approval label will identify the components of the MPCs. More information on NIOSH-approved CBRN PAPRs can be found on the NIOSH Fact Sheet (National Institute for Occupational Safety and Health (NIOSH), 2013).

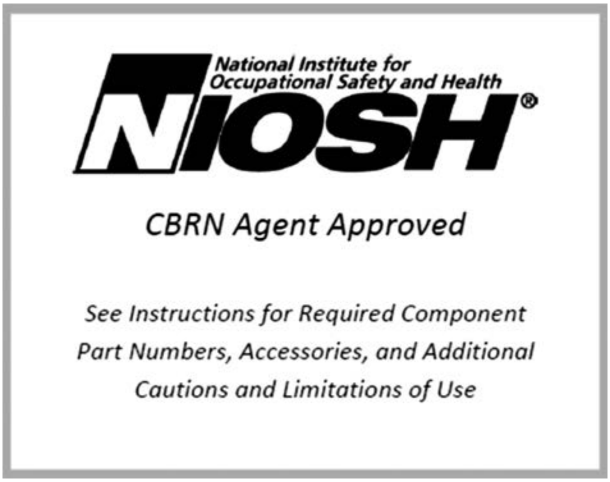
19.5 User Recognition and the NIOSH Certified Equipment List

Users should first inspect the respirator for labels indicating conformity and ensure the complete respirator is checked per the user instructions. Wearers can locate the NIOSH Testing and Certification (TC) number on the respirator and then contact NIOSH or the approval holder to assist in defining the full or partially identified NIOSH TC number. NIOSH has developed a fact sheet to help users identify important aspects of the approval label (Metzler and Szalajda, 2011).

Manufacturer-generated labels attached directly to the CBRN APR canister are most often adhesive labels. The printed labels appearing on the canister shipping container provide more condensed information. This guidance will help respiratory protection program administrators, managers, and respirator users in understanding the special features of NIOSH-approved CBRN APRs, PAPRs, and APERs. The most notable label required by NIOSH to be on a CBRN SCBA is the black and white label that reads "CBRN Agent Approved" in large font letters. This label can be anywhere on the SCBA backframe but is usually on the area around the first stage regulator/reducer or on respirator backframe and harness assembly. Figure 19.3 is a field photograph of what a first generation CBRN SCBA would carry as the *CBRN Agent Approved* adhesive label. Current generation CBRN SCBAs carry the same label, but without the CDC logo. SCBAs upgraded to CBRN protections will have the same NIOSH logo label and text, but with the word "Retrofit" added under the *CBRN Agent Approved* title.

Since 1994, NIOSH has maintained an online version of all respirator approvals (not just CBRN) (National Institute for Occupational Safety and Health, 2016b). CBRN respirator approval dates and descriptions are documented with the NIOSH Certified Equipment List (CEL). The NIOSH CEL allows a respiratory protection program administrator or respirator user to conduct both quick and advanced database searches. The search results confirm the existence of a NIOSH-approved respirator, validate field information concerning user recognition data of a deployed respirator, or identify what subcomponents (if listed) constitute a completely assembled CBRN respirator, as described in 42 CFR Part 84 and NIOSH CBRN respirator statements of standard.

Certificates of approval listed on the CEL are issued for RPDs that meet the applicable NIOSH requirements. These certificates of approval are not issued



National Institute for Occupational Safety and Health

NIOSH®

CBRN Agent Approved

See Instructions for Required Component Part Numbers, Accessories, and Additional Cautions and Limitations of Use

FIGURE 19.3
CDC/NIOSH *CBRN Agent Approved* Label example for SCBAs. Used between May 1, 2002 and December 5, 2005.

for any individual respirator components (e.g., CBRN Cap 1 canister, individual facepiece), but for the entire respirator assembly (National Institute for Occupational Safety and Health, 2011a, b, c). The CEL provides the user with seven sets of information per each listed SCBA respirator approval: the schedule of approval (13F), the approval number (which coupled with the schedule number makes up the NIOSH TC number), the respirator manufacturer/brand name, the model name of the SCBA, the rated time duration of the breathing air cylinder evaluated, the rated pressure value, the actual NIOSH approval issuance date, and the components icon hyperlink which lists the subcomponents that make up the individual respirator assembly per the NIOSH approval. Users are directed to a single fact sheet that details the selected respirator's approval specifics when they click on the approval number icon. CEL software enhancements to the 2016 edition will expand the Quick Search capability to search by TC number or by other single information factors such as brand name, model name, or listed protection (National Personal Protective Technology Laboratory, 2016b). The CEL is regularly updated as respirators are approved, made obsolete, or change status. As of 2016, a "Quick Search" on the CEL resulted in 246 approvals related to NIOSH-approved CBRN respirators (National Personal Protective Technology Laboratory (NPPTL), 2016c).

19.6 CBRN Respiratory Selection Criteria for Emergency Responders

NIOSH assists in identifying existing and evolving industrial hazards by listing the physical science properties in a reference guide, commonly known as the NIOSH "Pocket Guide" (National Institute for Occupational Safety and Health, 2016c). The 2016 release of the mobile application for the NIOSH Pocket Guide provides responders access to 634 chemical entries and links to recommended exposure level (REL) limits and IDLH values—information that aids respirator selection. For a CBRN respirator selection sequence, adapted and condensed from the NIOSH 2004 published selection, the user must answer queries regarding:

1. The intended use of the CBRN respirator (e.g., firefighting)
2. If the CBRN respirator is to be worn in an oxygen-deficient or other IDLH atmospheres
3. Anticipated concentration of single or multiple toxic agents in relation to the NIOSH REL or OSHA permissible exposure limit (PEL) or other recognized exposure limit applicable for that single agent or the most toxic agent of the multiple agents

4. If the CBRN contaminant is an eye irritant or can cause eye damage (which determines the fitting of the respirator)
5. The CBRN agent maximum hazard ratio value
6. Evaluation of assigned protection factor (APF) in relation to the maximum hazard ratio
7. Use in escape environments

Where the NIOSH Pocket Guide recommends the use of a SCBA, any suitable supplied air respirator (SAR) with integrated escape SCBA may be relied upon for protection; both respirators have an OSHA APF of 10,000. While providing this APF, CBRN SCBAs are significantly enhanced and improved from other NIOSH-approved SCBAs due to the live agent testing (LAT) (i.e., live agent chemist permeation/penetration) and LRPL (i.e., corn-oil aerosol particulate tests). In summary, NIOSH-approved CBRN respirators rely on traditional respirator selection factors because the CBRN respirators are essentially enhanced versions of industrial respirators awarded NIOSH approval.

19.7 Emerging Hazards

The United States must remain vigilant for new imminent threats that can appear and make sure the protection provided to responders and medical personnel is effective. Government agencies continue to monitor emerging CBRN threats so the performance of NIOSH-approved CBRN RPDs and other non-CBRN RPDs can be evaluated against newly discovered threats. Some biological threats that have recently emerged or became more prevalent include: Severe acute respiratory syndrome (SARS), Ebola, and the Zika virus. These emerging biological threats (and previously identified biological threats) are either a particulate or vapor droplet hazard. Therefore, NIOSH CBRN air-purifying devices (APRs and PAPRs) and filtering facepiece respirators (FFRs) with N-, R-, and P-series particulate filters are expected to provide protection against new biological threats.

NIOSH is continually working to develop and improve testing methods to enhance the respirator/human interface fit and provide better protection to respirator users from existing and emerging CBRN threats. When emerging threats are identified for which current NIOSH-approved RPDs are not adequate to provide user protection, NIOSH and its partners will develop new performance requirements and test procedures to determine appropriate respirators to use against these threats. NIOSH will publicly disseminate the requirements and procedures so that manufacturers can develop new respirator products to provide protection against emerging threats.

Disclaimer

Mention of commercial product or trade name does not constitute endorsement by the National Institute for Occupational Safety and Health. The findings and conclusions of this report are those of the authors and do not necessarily represent the views of the National Institute for Occupational Safety and Health.

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Evaluation of CBRN Canisters for Use in Post Fire Overhaul Environments: In Mask Analyte Sampling with Integrated Dynamic Breathing Machine

Leaton Jones and Eric A. Lutz

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20.1 Introduction

Firefighters have a greater risk of developing cancer which increases with duration of employment, highlighting the need to provide adequate workplace protection in all aspects of firefighting (Youakim 2006, Bates 2007). In addition to firefighters, research has shown that personnel who investigate the causal factors leading to a structural fire are also at increased risk of developing certain cancers (Davis et al. 2013). Fighting a fire can be broken down into three phases: first is the knockdown phase where all visible fires are extinguished, second is the overhaul where potential re-ignition sources are identified and further extinguished, lastly is the investigation phase when potential causes of the fire are identified.

During knockdown, firefighters are required to wear self-contained breathing apparatus (SCBA), but in many cases are not required to do so during overhaul or investigation. During the overhaul phase, firefighters are exposed to potentially harmful concentrations of residual combustion-related chemicals and particulates. These include carbon monoxide (CO), nitrogen dioxide (NO_2), and volatile organic compounds (VOCs). Within these classifications of chemicals, there are many known carcinogens such as benzene, 1,2-butadiene, formaldehyde, naphthalene, styrene, and toluene (Austin et al. 2001, Bolstad-Johnson et al. 2000). Within these groups formaldehyde is of particular concern given its status as a known human carcinogen and upper airway irritant (IARC 2004, Costa et al. 2013).

One approach considered by fire departments has been the use of air-purifying respirators (APRs) as a substitute for SCBAs during overhaul. Use of APRs could lessen the physical burden placed on firefighters and in some circumstances potentially be more cost effective than continuing to use SCBAs during the overhaul phase. To recognize and understand the potential risks of using APRs during overhaul, Burgess et al. (2001) compared the respiratory effects of firefighters who wore APRs with multipurpose cartridges during overhaul. This study identified acute changes in lung function and increased serum pneumoprotein indicating lower respiratory tract damage and suggesting that use of APRs fitted with multipurpose cartridges may not completely protect firefighters during overhaul. These findings are further supported by de Vos et al. (2006, 2009) who investigated APR cartridge performance during wild land fire scenarios.

To further clarify APR performance against overhaul contaminants, a study conducted by Anthony et al. (2007) demonstrated that the multipurpose cartridges tested in previous studies were not fully protective against combustion smoke contaminants. In an attempt to identify other filters with the potential to provide greater protection Currie et al. (2009) tested the effectiveness of three, commercially available, National Institute of Occupational Safety and Health (NIOSH) approved, chemical, biological, radiological, and nuclear (CBRN) canisters as well as one NIOSH-approved canister that was not permitted for CBRN use. This study found that these canisters provided greater protection when challenged with small scale, chamber-based, postfire, overhaul simulations when compared to the multipurpose cartridges. The canisters were able to reduce downstream concentrations of acetaldehyde, acrolein, benzaldehyde, formaldehyde, glutaraldehyde, butyraldehyde, crotonaldehyde, and cyanide to below NIOSH recommended exposure levels (RELs). To further elucidate the performance of CBRN canisters during overhaul, Jones et al. (2015) challenged the filters using large-scale prescribed burns using common household items. The results of this study were in contrast to the study conducted by Currie at al. (2009) in that the CBRN canisters were not effective at reducing formaldehyde below the REL.

The study described here expands on the work conducted by Jones et al. by introducing the use of a dynamic breathing machine (DBM) that accurately simulates the rate, volume, and oscillation of normal breathing patterns. It is hypothesized that the introduction of the breathing machine combined with in-mask analyte sampling will better demonstrate the protectiveness of CBRN canisters.

20.2 Methods and Materials

To determine the analyte reduction effectiveness of CBRN canisters/cartridges, a series of 12 burns with associated sampling durations was conducted at the Northwest Fire Districts (NWFD) training center (Marana, AZ, USA). Measured quantities of common household items were used during burns to simulate actual overhaul environments (Table 20.1). During each series of burns, fires were allowed to burn for approximately 15 minutes until maximum temperature and material combustion were achieved. Fires were then suppressed using water in accordance with standard firefighting procedures. After fire suppression, concentrations of CO were monitored until levels reached 30 ppm using an MSA Altair 4-gas meter (Pittsburgh, PA, USA), at which time sampling began using the DBM and two head forms fitted with full face respirators. This system allowed for side-by-side evaluation of two canisters/cartridges as well as ambient analyte measurements. Although NWFD standard operating procedures dictate the use of cross-draft ventilation before overhaul to reduce contaminant concentrations, this step was bypassed in an attempt to challenge the APRs with the greatest analyte concentrations possible (Northwest Fire District 2014).

Three commercially available NIOSH-approved CBRN canisters and one non-CBRN cartridge were used during testing. Canisters/cartridge were de-identified and provided a number (1–4). Each filter was used for a single iteration and replaced with an identical filter prior to the start of each new challenge. For each test iteration, a filter was randomly assigned to one of the two head forms (A or B).

Each head form was drilled to allow insertion of five Tygon tubes (Lima, OH, USA) around the nose and mouth area to allow for in-mask sampling, as well as a large stainless steel pipe for attachment to the breathing machine (Figure 20.1). Each head form was also fitted with an MSA Millennium full face mask respirator and quantitatively fit tested using an Occupational

TABLE 20.1

List of Household Materials Used During Testing

Material	Quantity	Dimensions
Fiberglass insulation	1	60.96 × 121.92 × 24.136 cm
Laminate flooring strip	2	19.8 × 128.5 × 0.7 cm
OSB particle board	1	122 × 122 × 1.9 cm
PVC pipe	1	2.54 cm (dia) × 30.48 cm
Sofa cushion	1	~61 × 61 × 10 cm
Textiles (cotton, nylon)	~0.2 kg	
Video cassette recorder/ compact disc player	1	~45.72 × 45.72 × 12.7 cm
Vinyl flooring strip	3	15.24 × 91.44 cm
Wood pallet	1	121.9 × 101.6 cm

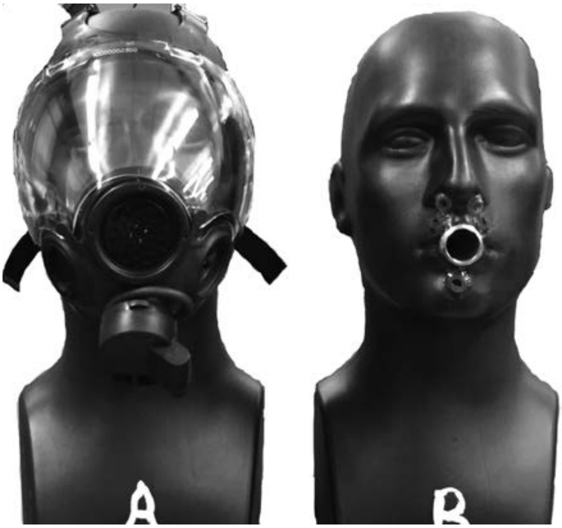

FIGURE 20.1
Front view of head forms "A" and "B".

Health Dynamics (OHD) Quantifit (Pelham, AL, USA). Head form "A" had a mean fit factor (FF) of 1,075 and head form "B" had a mean FF of 980 which exceeded the Occupational Safety and Health Administration's (OSHA) requirements (FF = 500) for full face respirators (OSHA 2004). Sampling from each head form, as well as ambient measurements, used three calibrated SKC personal sampling pumps (Eighty Four, PA, USA) and two Zefon Escort Elf personal sampling pumps (Ocala, FL, USA).

Use of the dynamic breathing machine (Warwich Technology Limited, Warwich, UK) (Figure 20.2) incorporated two physiologically relevant breathing patterns (80 Lpm, 2.5 L tidal volume, 32 breaths per minute/100 Lpm, 2.5 L tidal volume, 40 breaths per minute) which were randomized during each sampling iteration. These parameters were calculated using the International Organization for Standardization (ISO) standard for respiratory protective devices—Human factors—Part 1: Metabolic rates and respiratory flow rates (ISO/DTS 16976-1) (ISO 2015) and implemented using LabVIEW System Design Software (National Instruments, Austin, TX, USA). Prior to field use, leakage tests between the upper and lower chambers of the breathing machine were evaluated using laboratory gas. Samples were taken multiple times for 15 and 60 minute durations with no leaks detected. Verification was accomplished by increasing the breathing resistance on one of the head forms resulting in quantified leakage. All samples were taken with CBRN canisters in place.

Field assessments occurred after each fire was extinguished and CO concentrations fell to 30 ppm or below. The sampling system was placed inside the burn room via a wheeled cart approximately 1 m from the smoldering materials in a position that approximated a firefighters working breathing

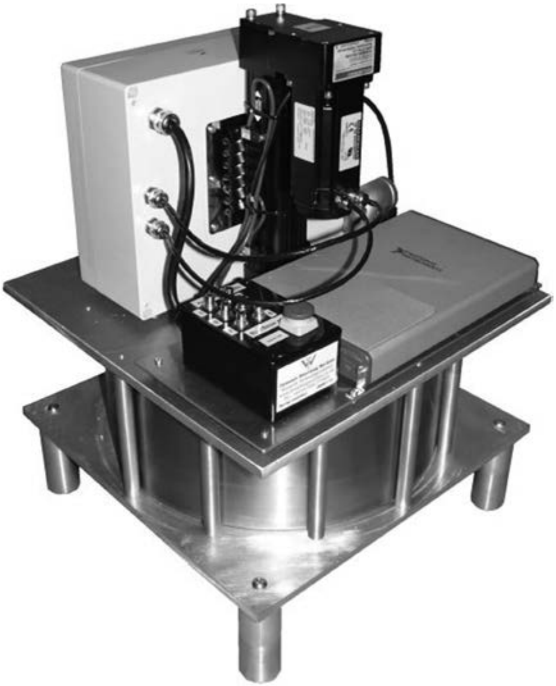

FIGURE 20.2
Dynamic breathing machine.

zone. Sampling durations were randomized for each test iteration (15 minutes or 60 minutes). Temperature and relative humidity (RH) were also monitored during sampling using a TSI VelociCalc model 9565 (Shoreview, MN, USA). A total of 55 analytes were measured during each of the test iterations, as detailed in Table 20.2. Analytical samples were sent to Galson Laboratories Inc., (East Syracuse, NY, USA) for analysis.

All statistical analysis was performed using Stata version 12.1 (College Station, TX, USA). Regression analysis was performed to evaluate for statistically significant relationships between analyte concentrations and temperature and/or RH. Two-tailed t-tests were also performed to determine if any significant differences existed between analyte concentrations within burn cycles. For all test, an alpha error threshold of 0.05 was applied.

20.3 Results

Sampling indicated the presence of 10 (18%) analytes in the ambient overhaul environment detected above the level of quantification (LOQ), including:

TABLE 20.2

Analytes Measured and Analysis Method

Analyte		Media/Analysis Method
Aldehydes	Acetaldehyde	ORBO 555/NIOSH 2016
	Benzaldehyde	
	Butyraldehyde	
	Crotonaldehyde	
	Formaldehyde	
	Isovaleraldehyde	
	Propionaldehyde	
	Valeraldehyde	
NO_2		226-40-02/NIOSH 6014
PNAH	Acenaphthene	PTFE/ORBO 43/NIOSH 5506
	Acenaphthylene	
	Anthracene	
	Benzo(a)anthracene	
	Benzo(a)pyrene	
	Benzo(b)fluoranthene	
	Benzo(e)pyrene	
	Benzo(g,h,i)perylene	
	Benzo(k)fluoranthene	
	Chrysene	
	Dibenz(a,h)anthracene	
	Fluoranthene	
	Fluorene	
	Indeno(1,2,3-cd)pyrene	
	Naphthalene	
	1-Nitropyrene	
	Phenanthrene	
	Pyrene	
	Acetone	
Respirable particulate		PW PVC/NIOSH 0600
VOC	Benzene	226-01/Multiple NIOSH
	n-Butyl acetate	
	Chlorobenzene	
	Chloroform	
	Cumene	
	Cyclohexane	
	Cyclohexanone	
	Cyclohexene	
	m-Dichlorobenzene	

(Continued)

TABLE 20.2 ***(Continued)***

Analytes Measured and Analysis Method

Analyte	**Media/Analysis Method**
o-Dichlorobenzene	
p-Dichlorobenzene	
1,1-Dichloroethane	
1,2-Dichloroethane	
Ethyl alcohol	
Ethyl benzene	
n-Hexane	
Methylene chloride	
Pentane	
n-Propyl acetate	
Tetrachloroethylene	
Tetrahydrofuran	
Toluene	
1,1,2-Trichloroethane	
Trichloroethylene	
Trichloroethylene	
Xylene	

acenaphthylene, acetaldehyde, benzene, benzaldehyde, crotonaldehyde, formaldehyde, naphthalene, phenanthrene, propionaldehyde, and respirable particulates (Table 20.3). Only formaldehyde was present above published American Conference of Governmental Industrial Hygienist (ACGIH) threshold limit value ceiling (TLV_C). While CO was relatively elevated, the MSA four-gas meter did not detect hydrogen sulfide, or explosive limits outside of recommended levels.

Of the 10 analytes detected above the LOQ in the postfire overhaul ambient environment, acetaldehyde and formaldehyde were the only analytes to be detected downstream of any filters on a fairly consistent basis. Benzene was detected downstream of one filter on the last burn cycle. Both analytes were present downstream of filters #3 and #4 while formaldehyde was only detected downstream from filters #1 and #2 (Table 20.4). Formaldehyde (Figure 20.3) and acetaldehyde (Figure 20.4) were reduced to below ACGIH reference thresholds (ISO 2015) in all cases (Figures 20.3 and 20.4).

All filters appreciably reduced concentrations of acetaldehyde during all test iterations. Filters #1, #2, and #3 reduced concentrations by (100%), and filter #4 reduced concentrations by (55%) for the 15-minute sampling duration. Filters #1 and #2 reduced acetaldehyde (100%), #3 (50%), #4 concentration (75%), for the 60-minute sampling duration.

All filters appreciably reduced concentrations of formaldehyde during all test iterations. Filter #1 reduced formaldehyde concentrations by (98%), #2

TABLE 20.3

Post-Fire Ambient Overhaul Analyte Concentrations (ppm) above LOQ

	Burn #1	**Burn #2**	**Burn #3**	**Burn #4**	**Burn #5**	**Burn #6**	**ACGIH**
Analyte	**CONC**	**CONC**	**CONC**	**CONC**	**CONC**	**CONC**	**TLV**
1. Acenaphthylene	0.0067	0.0035	0.003	0.004	0.003	0.0021	NE
2. Acetaldehyde	0.3	0.08	0.1	0.3	0.4	0.2	25[a]
3. Benzene				1			2.5[b]
4. Benzaldehyde		0.01					NE
5. Crotonaldehyde				0.07	0.06	0.02	0.3[a]
6. Formaldehyde	1.4	0.33	0.3	0.3	0.4	0.29	0.3[a]
7. Propionaldehyde				0.06	0.07	0.02	20
8. Naphthalene	0.019	0.0088	0.0066	0.02	0.0064	0.0051	NE
9. Phenanthrene		0.0005				0.0016	NE
10. Respirable particulate[c]					2.6	1	3

	Burn #7	**Burn #8**	**Burn #9**	**Burn #10**	**Burn #11**	**Burn #12**	**ACGIH**
Analyte	**CONC**	**CONC**	**CONC**	**CONC**	**CONC**	**CONC**	**TLV**
1. Acenaphthylene	0.001	0.0016	0.003	0.002	0.001	0.0007	NE
2. Acetaldehyde	0.03	0.097	0.1		0.02	0.07	25[a]
3. Benzene		0.1					2.5[b]
4. Benzaldehyde							NE
5. Crotonaldehyde							0.3[a]
6. Formaldehyde	0.07	0.1	0.2	0.2	0.07	0.1	0.3[a]
7. Propionaldehyde							20
8. Naphthalene	0.0053	0.0057	0.012	0.005	0.0033	0.001	NE
9. Phenanthrene	0.0005	0.0008			0.0007	0.0007	NE
10. Respirable particulate[c]	1	1.1					3

[a] Indicates ceiling limit.

[b] Indicates short-term exposure limit (STEL).

[c] 5.5 μm cutoff—ACGIH TLV and BEI book, Appendix B: Particles Not Otherwise Specified (PNOS), respirable. Concentrations are in mg/m^3.

NE, no established threshold limit.

(100%), #3 (81%), and #4 (79%), for the 15-minute sampling duration. Filter #1 reduced formaldehyde concentrations by (100%), #2 (94%), #3 (32%), and #4 (82%), for the 60-minute sampling duration (Table 20.5).

Assessment of temperature and RH during sampling showed a mean temperature of 38.7°C and a mean relative humidity (%RH) of 37.3%. Environmental conditions (temperature and RH) had minimal effect on ambient acetaldehyde and formaldehyde concentrations. Regression analysis showed a positive significant correlation between RH and concentrations of formaldehyde (Figure 20.5) $R^2 = 0.62$, ($p = 0.004$). Increases in temperature also showed a positive correlation for formaldehyde concentrations

TABLE 20.4

Canister/Cartridge Breakthrough Concentrations by Burn Number, Sampling Duration, and Analyte

Burn Number	Sampling Duration (Minutes)	Filter	Acetaldehyde CONC	Benzene CONC	Formaldehyde CONC
Burn #1	15	Filter #1			0.1
		Filter #2			
Burn #2	60	Filter #1			
		Filter #3	0.02		0.04
Burn #3	15	Filter #1			
		Filter #4			
Burn #4	15	Filter #2			
		Filter #3	0.09		0.1
Burn #5	15	Filter #3			0.08
		Filter #4			
Burn #6	60	Filter #2			
		Filter #4	0.07		0.18
Burn #7	60	Filter #1			
		Filter #2			0.01
Burn #8	60	Filter #3			0.02
		Filter #4	0.03		0.04
Burn #9	15	Filter #1			
		Filter #4			0.08
Burn #10	15	Filter #2			
		Filter #3			
Burn #11	60	Filter #1			
		Filter #3			
Burn #12	60	Filter #2			
		Filter #3	0.02	0.02	

($R^2 = 0.36$); however, this correlation was only marginally significant ($p = 0.052$ (Figure 20.6)).

20.4 Discussion

Burgess et al. (2001) and de Vos et al. (2006, 2009) observed adverse acute health effects associated with exposure to postfire environment exposure underlining the importance of providing adequate respiratory protection for firefighters. Furthermore, firefighters and fire investigators are at increased risk of developing certain cancers (ACGIH 2013, Daniels et al. 2014). In our live fire overhaul simulation study, formaldehyde was the only analyte

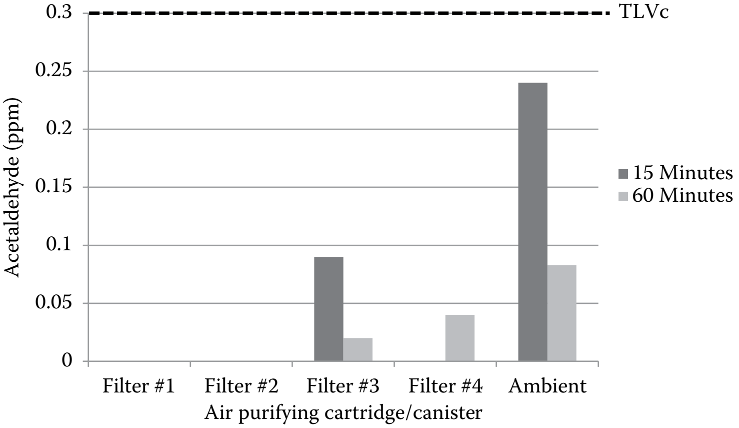

FIGURE 20.3
Aggregated mean acetaldehyde concentrations (ppm) by CBRN filter and sampling duration.

measured to be above ACGIH TLVs, while levels of acetaldehyde were present in both the ambient environment and post filter.

In 2004, the first NIOSH-approved CBRN canisters became commercially available in the U.S. market. Evaluation of CBRN canister effectiveness at filtering toxic components of smoke during overhaul started with the work conducted by Anthony et al. (2007) and Currie et al. (2009). These laboratory-scale evaluations of mock overhaul environments using limited quantities of household items in a smoke chamber showed that APRs fitted with CBRN canisters held promise in providing an alternative means of respiratory protection when SCBAs were unavailable, or impractical.

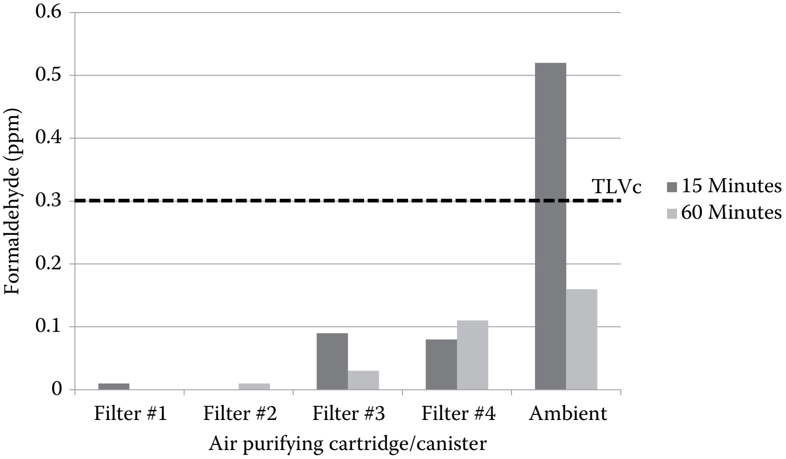

FIGURE 20.4
Aggregated mean formaldehyde concentrations (ppm) by CBRN filter and sampling duration.

TABLE 20.5

Mean (ppm) and Percent Reduction from Ambient by CBRN Filter and Sampling Duration

			Filter #1		Filter #2		Filter #3		Filter #4	
Analyte	**Sampling Duration (Minutes)**	**Ambient**	**Conc.**	**%**	**Conc.**	**%**	**Conc.**	**%**	**Conc.**	**%**
Acetaldehyde	15	0.2	0	100	0	100	0	100	0.09	55
(ppm)	60	0.08	0	100	0	100	0.04	50	0.02	75
Formaldehyde	15	**0.42**	0.01	98	0	100	0.08	81	0.09	79
(ppm)	60	0.16	0	100	0.01	91	0.11	32	0.03	82

Building on the work of Anthony et al. (2007) and Currie et al. (2009), work conducted by Jones et al. (2015) utilized full-scale burns using various common household items and assessed postfire filtering performance of three CBRN canister and one cartridge identifying performance at 15-, 30-, and 60-minute exposures at respiratory relevant rates. This study built on that previous work conducted by Jones et al. using similar methodologies, but integrating the use of a DBM to accurately simulate physiological breathing patterns (rate, tidal volume, and breath cycle) as well as head forms fitted with full face respirators.

The studies conducted by Anthony et al. (2007) and Currie et al. (2009) suggested that in laboratory-simulated overhaul environments, CBRN canisters effectively reduced all detected analytes to below TLVs. In contrast, the work conducted by Jones et al. (2015) found that formaldehyde and respirable particulates were not effectively reduced below TLVs. However, the current work evaluating similar filters during postfire overhaul using structurally relevant materials showed similar results to the studies conducted by Anthony and Currie, with CBRN filters reducing analytes to below TLVs.

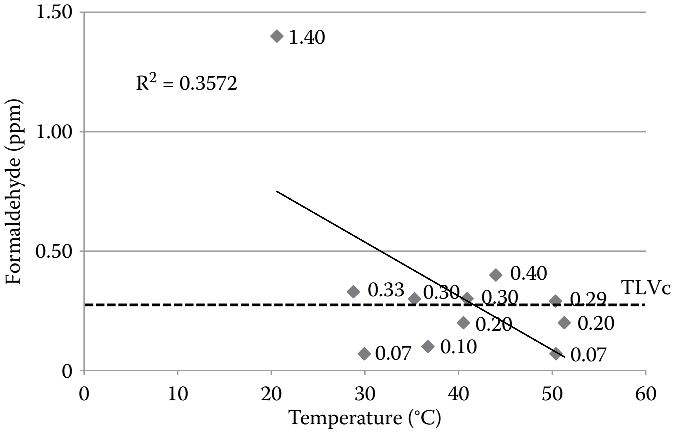

FIGURE 20.5

Linear regression of formaldehyde (ppm) and temperature (°C).

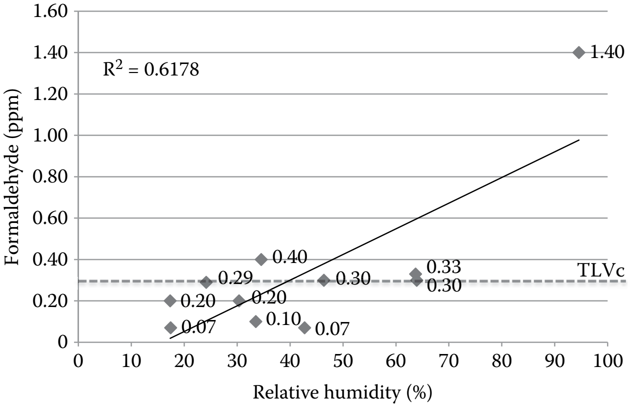

FIGURE 20.6
Linear regression of formaldehyde (ppm) and RH (%).

The discrepancies observed for post-filter formaldehyde concentrations between this study and the previous study conducted by the same research team could be attributed to several factors. First, this study's internal "ambient" maximum mean temperature during burns was lower than the previous study (167°C vs. 135°C). This could have had the effect of incomplete combustion of materials in turn lowering ambient analyte concentrations. Additionally, because of the time of the year this study was conducted, condensation was present on the burn materials at the beginning of the sampling days which could further reduce combustion. Another consideration is that this study used a DBM which integrated oscillatory flow and may have reduced the stress on the CBRN filters when compared to the constant flow of the previous studies. Stress from constant flow could have compromised the integrity of the filter's carbon bed due to its friable nature biasing formaldehyde and respirable particulates and resulting in higher breakthrough values. Finally, this study's mean ambient formaldehyde concentration (0.22 ppm) was 8.9 times that of the previous study's mean ambient formaldehyde concentration (1.96 ppm).

Although post-filter respirable particulate concentrations were reduced to levels below the LOQ, challenge concentrations could have been biased low as overhaul operations were not being conducted (i.e., prodding combusted materials). In a study conducted by Baxter et al. (2010) it was reported that respirable particulate concentrations were greatly increased during overhaul-related activities that disturbed burned materials. It should also be considered that studies conducted by Nelson and Correia (1976) and Wood (1985) reported that increases in temperature and humidity negatively affected the service life and efficacy of APRs. Wood (1985) reported that an increase of 5°C above NIOSH bench test methods (25 ± 2.5°C) with corresponding increases in humidity doubled the penetration of methyl iodide. Further, Nelson and Correia (1976) reported that increasing humidity depressed the service life of APRs especially above 65% RH. Although these studies were not conducted on CBRN filters, analyte breakthrough could be attributed to the environmental conditions observed during sampling.

The methods used in this study to evaluate the effectiveness of CBRN filter capacity intentionally differed from those used by NIOSH for certification. Compared to the NIOSH methods (Federal Register 1996), this study had a mean ambient test temperature of 38.8°C (range 14.3–55.3°C) which was greater than NIOSH's bench test temperature of 25 ± 2.5°C. Additionally, %RH for this study was generally lower than those used by NIOSH (50% ± 5%) with a mean ambient test %RH of 37.3 (range 15.4%–98.9%RH). Lastly, this study used oscillatory flow at 80 and 32 Lpm which differed from NIOSH's bench tests of continuous flows of 64 and 100 Lpm. These changes from the standard testing methods of CBRN certification reflect environments and physiological performances reported by firefighters performing overhaul.

Throughout this study every effort was made to ensure that variability of burn materials was minimized. Although some variations in the sizes and types of electronics and textiles were inevitable, variability in the concentrations of ambient formaldehyde was not significant ($p = 0.215$). Additionally, this study was conducted in the winter months which may have had an effect on lower ambient sampling temperatures as well as condensation on burn materials hindering complete combustion. These variables could have had the effect of lower analyte challenge concentrations than experienced previously by this research team, in turn reducing filter breakthrough concentrations.

20.5 Conclusions

At the ambient analyte concentrations generated during this study, the CBRN filters evaluated effectively reduced levels of hazardous chemicals and respirable particulates to below occupational exposure limits during simulated overhaul. Acetaldehyde and formaldehyde were the only two chemicals present fairly consistently post filter. While filter performance has not been evaluated past 60 minutes, this study indicates that CBRN filters are effective at reducing typical overhaul chemical compounds. Although reduced to below occupational exposure limits at the currently tested ambient levels, the carcinogenicity of formaldehyde combined with breakthrough observed at higher concentrations warrants the recommendation that firefighters continue to use SCBAs during postfire activities.

Further research should be conducted that evaluates the effectiveness of CBRN canisters during actual overhaul. Additionally, it has been over a decade since postfire analyte concentrations were quantified at actual structural fires. These studies should be duplicated as construction materials and common household items have changed to greater quantities of artificial plastics and particle board. Lastly, due to the rising concern of postfire environmental health in those who investigate fires, quantification of postfire chemical compounds should be conducted at times relevant to these individuals.

Acknowledgments

This work could not have been conducted without the partnership of the professional firefighters of the Northwest Fire District and the scientific collaboration of the National Institute of Occupational Safety and Health, National Personal Protective Technology Laboratory team (Contract #254-2014-M-60366).

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Section VII

Emerging Issues

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21

Respiratory Protection against Nanoparticle Exposure in Workplaces

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21.1 Introduction

Nanoparticles are produced by natural sources and industrial processes (Biswas and Wu, 2005). A nanoparticle is defined as a nano-material with all three external dimensions ranging in size from approximately 1–100 nm (ISO/TS, 2009). Engineered nanoparticles with unique physical and chemical properties have been utilized for numerous applications. The rapid growth of nanotechnology has increased the production of engineered nanoparticles in industrial workplaces. High concentrations of nanoparticles have been reported in some workplaces (Elihn and Liden, 2011; Gomez et al., 2013; Guerreiro et al., 2014; Johnson et al., 2010; Methner et al., 2010, 2012). Inhalation is the most common route of nanoparticle exposure and is a potential risk during various processes including cleaning engineered nanomaterials from dust collection systems, spills, and disposal. Nanoparticles have been implicated in human health and environmental effects (Cena et al., 2015; O'Shaughnessy, 2013; Sarkar et al., 2014) suggesting that respiratory protection is needed when engineering and administrative controls are not sufficient or feasible.

The Occupational Safety and Health Administration (OSHA) respiratory protection standard requires that National Institute for Occupational Safety and Health (NIOSH) approved respirators be used for protection in industrial workplaces (Federal Register, 1998). For respirators to provide the expected level of protection, employers must implement a complete respiratory protection program including the selection of appropriate respirators for exposed workers. The protection provided by a respirator is estimated based on the OSHA definition of the assigned protection factor (APF) (OSHA, 2006). The APF is the workplace level of respiratory protection that a respirator or class of respirators is expected to provide to employees when the employer implements a continuing, effective respiratory protection program (Federal Register, 1998). The APF accounts for all expected sources of penetration including filter media, face seal, and exhalation valves. To achieve a desired APF value, respirator selection is recommended by the criteria described in the "NIOSH Respirator Selection Logic," which was developed based on toxicological, safety, and other relevant information (NIOSH, 2004).

Workplace protection factor, (WPF) similar to APF, is described as the protection provided in a real workplace, under the conditions of that workplace, by a properly selected, fit tested, and functioning respirator while or when it is correctly worn and used (American Industrial Hygiene Association Respiratory Protection Committee, 2002). The estimates of WPFs for different types of respirators in a variety of workplaces have been described (Bidwell and Janssen, 2004; Cho et al., 2010; Janssen and McCullough, 2010; Zhuang et al., 2003).

Because of the difficulties in measuring WPF for subjects wearing respirators in actual workplaces, a simulated workplace protection factor (SWPF) is measured in a laboratory setting using test exercises simulating normal workplace activities. Several studies have reported the SWPF for N95 filtering facepiece respirators (FFRs) (Coffey et al., 2004; Hauge et al., 2012; Lawrence et al., 2006; Lee et al., 2008). In one study, the SWPF for 18 N95 FFRs was obtained using five different fit testing methods (Coffey et al., 2004). The fifth percentile SWPF values ranged from 1.3 to 48 for the different models. This study also showed that passing the fit test generally resulted in an increase in SWPF. Another study employed a PortaCount® Plus (TSI, Inc. St. Paul, MN) to measure the SWPFs for 15 models of N95 elastomeric half-facepiece respirators (EHRs), 15 models of N95 FFRs, and 6 models of surgical masks (Lawrence et al., 2006). For EHRs and FFRs, the geometric mean (GM) of SWPF values were 35.5 and 20.5, with fifth percentile values of 7.3 and 3.3, respectively. Some studies (Lee et al., 2008; Reponen et al., 2011) have described a protection factor (PF) similar to SWPF except that the test exercises are not believed to represent real workplace activities. There is no prescribed set of exercises for measuring either PF or SWPF.

Respiratory protection against nanoparticles has been reviewed (Shaffer and Rengasamy, 2009). A limited number of studies have reported the SWPF for nanoparticles (Hauge et al., 2012; Lee et al., 2008; Rengasamy et al., 2014; Vo et al., 2015). Lee et al. (2008) have measured the PF values for nanoparticles as well as larger size particles in a controlled environmental chamber supplemented with NaCl aerosol. Twelve subjects tested four N95 FFR models, and the outside and inside aerosol concentrations were measured using an electrical low-pressure impactor (ELPI), while performing OSHA fit testing exercises. The ELPI measures the particle concentration of different aerodynamic diameter size particles. The results showed that PF values were lower for ~78–130 nm size range particles than for the other size particles and increased with increasing particle sizes up to 1260 nm (Lee et al., 2008). The smaller PFs for nanoparticle sizes in the study indicated lower WPF values in a nanoparticle work environment. Another study described SWPF measurement using a PortaCount® (TSI, Inc.) with a N95 Companion, which measures particles of 30–60 nm sizes (Hauge et al., 2012). The GM SWPF values ranged from 172 to 1073 for all exercises and test subjects.

Recent publications from our laboratory described the protection performance of FFRs and EHRs for nanoparticles at simulated workplace conditions (Rengasamy et al., 2014; Vo et al., 2015). Because of the similarities in measuring respirator performance with these two studies, the PF measured in Study 1 (Rengasamy et al., 2014) is described as a SWPF throughout this chapter. The test protocols in the two studies were different with respect to aerosol characteristics, aerosol exposure, and test equipment. Study 1 (Rengasamy et al., 2014) measured the SWPF values for N95 FFRs worn by test subjects in two different test laboratories with different concentrations of nanoparticles. In Study 2 (Vo et al., 2015), subjects were tested in an environmental chamber supplied with NaCl aerosol continuously. The SWPF values for different size particles in the 10–400 nm range were measured. The results obtained in the two studies are described.

21.2 Methods

The SWPFs for FFRs and EHRs were measured at two different simulated workplace conditions. In Study 1, subjects were exposed to laboratory aerosol supplemented with NaCl aerosol when necessary, in two different laboratories (6 m × 6 m × 2.5 m) (Laboratory 1 and Laboratory 2) for SWPF measurement. Study 2 tested the subjects in an aerosol chamber (2.5 m × 2.5 m × 1.5 m) supplied with polydispersed NaCl aerosol continuously, in a different laboratory. The three laboratories are located in different or separate buildings at the NIOSH facility in Pittsburgh, PA, USA. Further details of the studies are described below.

21.2.1 Study 1

21.2.1.1 Respirators

Five N95 FFR models (Table 21.1) were tested in the study, which included 3M (Model 8000), 3M (9210), Kimberly-Clark (Model 170/174), Sperian-Willson (Model SAF-T-FIT, 10FL), and 3M (8511). The respirators were labeled as A, B, C, D, and E, respectively. Only one model (3M 8511) had an exhalation valve. These models were chosen based on previous use in our laboratory.

21.2.1.2 Subjects

Thirty-five test subjects tested five N95 FFR models in Laboratory 1 and Laboratory 2 as described previously (Rengasamy et al., 2013, 2014). The subjects were not fit tested before SWPF measurement. The facial dimensions of the test subjects were measured and the NIOSH bivariate panel (Zhuang et al., 2008) was used for placement of subjects in specific face length and face width cells. The participants in the study were experienced respirator users, who had previously participated in fit test studies. This study was approved by the NIOSH Institutional Review Board and all subjects gave written consent to participate.

TABLE 21.1

GM, GSD, and Fifth Percentile Values of SWPF for the Five N95 FFR Models Tested in the Two Laboratories

		SWPF			
		Laboratory 1		Laboratory 2	
N95 Model	Total Number of Tests	GM ± GSD	Fifth Percentile	GM ± GSD	Fifth Percentile
A	105	29.1 ± 1.9	9.9	32.3 ± 2.1	9.8
B*	105	115.1 ± 2.4	28.0	156.4 ± 2.5**	33.7
C	105	44.1 ± 1.8	16.8	43.3 ± 1.6	20.4
D	105	39.1 ± 1.4	21.7	36.4 ± 1.5	18.3
E*	105	92.1 ± 2.1	27.8	111.2 ± 2.2**	30.9

* Significantly different from other models.

** Significantly different from Laboratory 1 for this model.

21.2.1.3 Laboratory (Ambient) Aerosol Measurement

A Scanning Mobility Particle Sizer™ (SMPS, TSI, Inc.) with a long differential mobility analyzer (Model 3081) was used to measure the size distribution of particles in the 10–700 nm size range in both laboratories. The SMPS was programmed to scan the particle size distribution for 135 seconds, three times, every hour from 8:00 a.m. to 4:00 p.m. Monday through Friday (laboratory testing times). From the SMPS scans, the average count median diameter (CMD) of the laboratory aerosol for each day was obtained.

Laboratory 1 and Laboratory 2 were located in different buildings separated by ~100 meters. Other laboratories in the buildings were doing experiments not related to the work and particles generated by processes in those laboratories could have contributed to the particle size distributions in the two SWPF test laboratories. A minimum particle concentration of 1000 particles/cm^3 in the test laboratories was used during testing. When needed, a 2% NaCl solution was aerosolized using a particle generator (TSI Model 8026) to supplement particle concentration levels in the laboratories.

21.2.1.4 Subject Testing

SWPF was measured using a PortaCount® Pro+ (Model 8038, TSI, Inc.) with PortaCount mode turned on (N95 mode turned off) by measuring the in-mask particle concentration and ambient concentration during subject testing in each laboratory. The SWPF was defined as a quantitative measurement of the ratio of the particle concentrations in the ambient air (C_{out}) to the in-mask (C_{in}) of the respirator. A "FitPro™ Fit Test software" (TSI) was used to provide a fully automated data processing, recording, and storage during the testing. All SWPF data, including test subject and respirator identifiers were downloaded into a pre-established database and were accessed after the test for analysis. The test data were also recorded manually for immediate review by project personnel.

The test operators were experienced in fit testing subjects. Different test operators administered the SWPF measurement in each of the two laboratories. This study was double-blind in that the test operators in each laboratory did not know the results obtained by the other laboratory. Subjects were trained using the manufacturers' user instructions on the proper donning and user seal check procedures. Prior to SWPF testing, the subjects wore each FFR for a 5 minute period for acclimatization of the respirator on the face. The subjects subsequently connected the PortaCount sample line to the connector on the respirator, donned the FFR, and made any necessary adjustments to the FFR until they felt they had achieved a good fit and could subsequently pass the user seal check without detecting a face seal leak. The test administrators verified that the FFR was being properly donned by the test subject and provided the necessary training to assure conformance to the user instructions. When ready, the subjects gave the test administrator a signal that she or he was ready to start the test. The drag/weight of the sample tubing and its potential effect on the FFR fit were minimized by the test subject holding the sample line with one hand away from the front of their chest. For SWPF measurement, the eight exercises prescribed in the standard OSHA fit test protocol (OSHA, 1998) were used. The exercises were performed in the following order: (1) normal breathing, (2) deep breathing, (3) turn head side to side (4) move head up and down, (5) speak out loud (recitation of the "rainbow" passage), (6) reach for floor and ceiling (7) grimace, and (8) normal breathing. When testing was completed, the subject removed the FFR, redonned the same FFR, and tested two more times consecutively with a 5 minute break between the tests.

21.2.1.5 SWPF Measurement

Subjects were tested in a random order in Laboratory 1 or Laboratory 2 and completed the test in the other laboratory on the same day. A new sample of each respirator model was tested by the subject in each laboratory following the identical donning procedure.

The PortaCount calculated the SWPF for each individual exercise ($SWPF_i$),

$$SWPF_i = \frac{\text{Ambient concentration}}{\text{In-mask concentration}}$$

and then obtained the harmonic mean for seven exercises except the grimace as shown below with "n" representing the number of exercises.

$$SWPF = n\left(\sum_{i=1}^{n} \frac{1}{SWPF_i}\right)^{-1}$$

Thirty-five subjects tested each FFR model three times (35 subjects × three donnings × five FFR models) to give a total number of 525 SWPF tests in each laboratory. The performance of N95 FFRs was assessed using the fifth percentile SWPF values. The fifth percentile SWPF value was calculated using the formula GM/geometric standard deviation $(GSD)^{1.645}$. The unadjusted GM and GSD estimates do not account for "subject" effects. Statistical significance tests were based on a mixed effects analysis of variance (with "subject" as a random effect) using specific contrasts for hypothesis testing. R software was used for this analysis (R Core Team, 2013) with the "nlme" package (Pinheiro et al., 2013). The CMD values measured in the two laboratories were analyzed by a two-sided t-test (Shapiro–Wilk).

21.2.2 Study 2

21.2.2.1 Test Subjects and Respirators

Twenty-five subjects (13 females and 12 males) were tested for SWPF measurement under simulated workplace activities (Vo et al., 2015). The age of the panel members ranged from 19 years to 65 years. Placement of subjects in specific cells in the test panel, study approval, and subjects consent for participation are similar to those described in Study 1.

Eight NIOSH-approved respirator models, including two respirator types (FFRs and EHRs) and two classes of filters (N95 and P100) were selected for the test based on their common use in the workplace, and their commercial availability. The respirator models in each series (class of filter) were randomly assigned labels A or B.

21.2.2.2 Preparation of Test Aerosols and Test Equipment

For fit testing, a 2% NaCl solution was aerosolized with a particle generator (Model 8026, TSI, Shoreview, MN, USA) outside of the chamber in the laboratory room. A PortaCount® (Model 8038, TSI) was used for fit testing subjects. For SWPF measurement, an aerosol chamber testing system consisting of an aerosol generation setup, an exposure chamber system, and a particle detector setup was used. The aerosol generation setup included a six-jet atomizer (Model 9306, TSI), a Kr-85 aerosol neutralizer (Model 3054, TSI), and an ultrafine condensation particle counter (UCPC, model 3776, TSI). The exposure chamber system consisted of a chamber (Model 222-6, Dynatech, Albuquerque, NM, USA), a humidity/temperature sensor (Model RHXL3SD, Omega Engineering, Stamford, CT, USA), circulation fans located in each upper corner, and a 14-cm diameter exhaust port. The exposure chamber had sufficient space for a human subject wearing a respirator to perform an SWPF test consisting of several exercises comfortably. The particle detector component consisted of two scanning mobility particle sizers (SMPS, Model 3080 with CPC-3772, TSI), which measured the upstream (outside the respirator) and downstream (inside the respirator) concentrations simultaneously.

21.2.2.3 Fit Test Procedure

Subjects were fit tested using a PortaCount® under laboratory conditions (outside the exposure testing chamber). A particle generator (Model 8026) was used to keep room concentration levels between 3000 and 8000 particles/cm^3 for the fit test. When the laboratory particle concentrations reached the designated level, subjects trained by a test operator donned the FFR or EHR and connected the particle-sample lines to the PortaCount. To ensure the respirator was properly donned, the test operator was required to help test subjects don the respirator, adjust its head straps, reshape its metal nosepiece (if equipped), and perform the standard respirator user seal check. Subjects performed the OSHA standard fit test (OSHA, 1998) exercises as described in Study 1. A fit factor (FF) value $\geq$100 was considered a pass. After passing the fit test, the subject continued to wear the respirator and was escorted to the exposure chamber for the SWPF test.

21.2.2.4 SWPF Test Procedure

A 0.2% NaCl solution was aerosolized using a six-jet atomizer at a dispersion of 30 L/min. The output aerosol was dried with 30% dilution air in an atomizer self-contained dilution system, followed by neutralization with the Kr-85 charging source before entering into the exposure chamber. The aerosol in the chamber was mixed by four internal fans of the chamber. Throughout the experiment, the UCPC monitored the chamber concentration, and a humidity/temperature sensor monitored the relative humidity (RH) and temperature. During particle sampling, NaCl aerosol particles were continuously dispersed into the chamber, while the exhaust port was in the open position to remove excess air and maintain neutral pressure. When the NaCl aerosol concentration in the chamber stabilized at the exposure level of approximately 2×10^5 particles/cm^3, the subject donned with the respirator entered the exposure chamber for the SWPF test. The in-mask sample line was connected to the respirator once inside the chamber.

The SWPF test was performed using six exercises, 3 minutes each in the following order: (1) normal breathing, (2) deep breathing, (3) moving head side to side, (4) moving head up and down, (5) bending at the waist, and (6) a simulated laboratory-vessel cleaning motion. SMPS measured the particle concentrations outside and inside of respirator for 2 minutes during each exercise. The simulated laboratory-vessel cleaning motion involved the subject moving his or her arms forward-down and backward-up in a shovel-scooping-like fashion, with a distance of about 30 cm at a rate of approximately one completed motion every 5 seconds. Test data were recorded and SWPF for the six exercises was calculated as described in Study 1.

This procedure was repeated for all eight respirator models. Three replicate tests were conducted for each respirator model for each subject for a total of 600 tests. The SWPF data analysis was performed using an analysis of variance (ANOVA) model provided by the Statistical Analysis System version 9.3 (SAS Institute Inc., Cary, NC). The ANOVA was also used for analyzing statistical computations, including overall SWPF, GM SWPFs, and all pairwise SWPF comparisons. P-values of <0.05 were considered significant. The fifth percentile SWPF was computed from the formula $\text{GM}/\text{GSD}^{1.645}$.

21.3 Results

21.3.1 Study 1

Thirty-five subjects tested the five N95 model FFRs three times (35 subjects × five FFR models × three donnings) for a total number of 525 SWPF tests in each laboratory. Table 21.1 shows the GM of SWPFs and GSD for the five N95 model FFRs. The GM SWPF ranged from 29.1 to 115.1 in

Laboratory 1 and 32.3 to 156.4 in Laboratory 2. The GM SWPF values for models B and E were significantly ($p \leq 0.05$) larger than the other models in both laboratories. The GM SWPFs for both B and E in Laboratory 1 were significantly ($p \leq 0.05$) smaller than in Laboratory 2. The other three models showed only marginal differences in the GM SWPF values between the two laboratories. The fifth percentile SWPF value was calculated using the formula $GM/GSD^{1.645}$. For both laboratories, the fifth percentile SWPF values for all models were ≥ 10, except for model A. The models B and E showed larger fifth percentile values than the other models, in both laboratories. The fifth percentile SWPFs for respirator models B and E were slightly smaller in Laboratory 1 than in Laboratory 2.

Aerosol size distribution and the CMD were obtained for all test days (27 days in Laboratory 1 and 32 days in Laboratory 2). The mean CMDs were 82 ± 19 nm in Laboratory 1 and 131 ± 23 nm in Laboratory 2. The CMD value represents 50% of particles above and below that size. The CMD in Laboratory 1 was significantly ($p \leq 0.05$) lower than the CMD in Laboratory 2. The CMD values were <100 nm in Laboratory 1 on 93% of SWPF test days compared to 18% of test days in Laboratory 2. The lower CMD values measured in Laboratory 1 indicate the presence of a relatively higher concentration of nanoparticles in Laboratory 1 than in Laboratory 2. Table 21.1 shows the GM, GSD, and fifth percentile SWPF values for the five N95 model FFRs tested in the two laboratories.

21.3.2 Study 2

Based on the particle size range of interest for the respirator performance against nanoparticles, the size distribution range of 10–400 nm was measured. Within this size range, 96% of particles were centered between 28 and 350 nm with a mode of 82 nm, a CMD of 60 nm, and GSD of 2.88.

All subjects passed the fit test with all N95 and P100 EHR models (all FF values ≥ 100). For FFRs, while all subjects passed the fit test with two P100 FFR models, some subjects failed the fit test during the first trial with the two N95 FFR models. Therefore, a test operator helped these test subjects with donning the N95 FFRs and reshaping the metal nosepiece to ensure the subjects passed their fit test with the N95 FFRs before performing an SWPF test.

The respirator performance statistics for the different respirator filter classes (N95 and P100) for both EHR and FFR types as determined by the SWPF testing across the nanoparticle size range (10–100 nm) were determined and compared to the larger size range of 100–400 nm (Table 21.2). The results show that the GM SWPFs for nanoparticles were significantly larger than those of larger particles (100–400 nm) (all P-values <0.05), except N95 EHRs ($P = 0.06$). In general, the GM SWPFs in both ranges had a similar trend order with the highest for the P100 EHRs, followed by P100 FFRs, N95 EHRs, and N95 FFRs (Table 21.2). All P100 class respirators in both ranges provided significantly higher SWPF values compared to class N95 respirators

TABLE 21.2

GM-SWPF and Fifth Percentile Values: Nanoparticles versus Larger Particle Range

		Size Range: 10–100 nm		Size Range: 100–400 nm	
Respirator Type	**Class of Filter**	**GM_SWPF (± GSD)**	**Fifth percentile**	**GM_SWPF (± GSD)**	**Fifth percentile**
FFR	N95	112 ± 2.5	45	83 ± 3.0	14
	P100	6,595 ± 4.2	1,574	3,439 ± 4.5	292
EHRs	N95	196 ± 2.7	72	202 ± 1.9	68
	P100	11,800 ± 3.1	3,777	6,780 ± 2.9	1,199

(all P-values <0.05) for both EHR and FFR types (Table 21.2). The results also show that P100 and N95 EHRs exhibited better performance than P100 and N95 FFRs (all P-values <0.05), respectively.

The average SWPF value as a function of particle diameter for the four combinations of filter classes and respirator types (N95 FFRs, P100 FFRs, N95 EHRs, and P100 EHRs) was evaluated. The SWPFs decreased with increasing particle diameter from 10 to 400 nm size range for all respirator types. The SWPFs values were larger for different size particles for the P100 EHRs, followed by P100 FFRs, N95 EHRs, and N95 FFRs. All P100 class respirators provided significantly higher SWPF values compared to N95 class respirators (all P-values <0.05) for both FFR and EHR types.

21.4 Discussion

The data from Study 1 (Rengasamy et al., 2014) showed a relationship between SWPF and particle size distribution. Two N95 FFR models (B and E) showed that the GM SWPFs in Laboratory 1 were significantly ($p \leq 0.05$) smaller than the values in Laboratory 2, while the other three models showed only marginal or no effect. The particle size distribution showed that the average CMD value for each day was <100 nm in Laboratory 1 on 93% of test days compared to 18% in Laboratory 2. The mean CMD (for all SWPF test days) of 82 nm in Laboratory 1 was significantly ($p \leq 0.05$) smaller than 131 nm in Laboratory 2, indicating the presence of a relatively higher concentration of nanoparticles in Laboratory 1. The SWPF measurement with test subjects showed that the GM SWPFs and the fifth percentile values for models B and E increased with an increase in the CMD of ambient aerosols. The data obtained in the study show the impact of particle distribution on SWPF of N95 FFRs.

The results obtained in the study are corroborated by the findings reported in the literature (Holton and Willeke, 1987; Lee et al., 2008; Reponen et al., 2011). Particle size-dependent leakage was measured for particle sizes between 0.07

and 4.4 μm through a negative pressure half-mask respirator worn by a human subject (Holton and Willeke, 1987). From the data obtained in the study, the authors showed that the ratio of percentage leakage for exposure aerosols with CMDs of 0.28 and 2.2 μm could be as large as 5:1 (Holton and Willeke, 1987), indicating lower PFs for exposure aerosols with smaller CMD values. Recent studies investigated the particle size dependency of PFs using different technologies. In one study, the PF values were measured for four N95 model FFRs worn by human subjects for eight different particle size ranges between 40 and 1260 nm using an ELPI (Lee et al. 2008). The ELPI measurement is based on particle numbers of different aerodynamic diameter size particles. Their results showed that the PF values were lowest for 78–130 nm aerodynamic diameter particles and increased with increasing particle sizes up to 1260 nm. Similarly, the fifth percentile WPFs for 0.7–10 μm diameter particles showed an increase from 16 to 223 for N95 FFRs using an optical particle counter (OPC) (HHPC-6, Hach Company, Loveland, Co) (Cho et al. 2010). The SWPFs obtained with a PortaCount® Pro+ in Study 1, the PFs measured using the ELPI (Lee et al., 2008), and the WPFs obtained by the OPC method (Cho et al., 2010) consistently showed the particle size dependency of PF or WPF.

On the other hand, the data obtained in Study 2 showed decreasing SWPF values with increasing particle sizes from 10 to 400 nm range for all N95 and P100 class FFR models and EHR models (Vo et al. 2015). The SWPF values were relatively larger for 10–30 nm particles compared to ~50 nm size particles, which is consistent with the PF data from previous studies (Lee et al., 2008; Reponen et al., 2011). The reference studies (Lee et al., 2008; Reponen et al., 2011) showed higher PF values for smaller and larger than the most penetrating particles, which were attributed to the total inward leakage (TIL) for different size particles. On the other hand, the SWPF results of Study 2 showed a decreasing trend for particles in the 10–400 nm size range for all respirators. The authors explained that higher RH conditions inside the breathing area of respirators contribute to the growth of different size particles, which increases the concentration of larger size particles with a concomitant decrease in the concentration of smaller size particles. The results from the study showed lower SWPF for larger size particles than for smaller size particles, which contradict the current understanding of respiratory protection for different particle sizes, and the results described in the literature (Holton and Willeke, 1987; Lee et al., 2008; Rengasamy et al., 2014; Reponen et al., 2011).

The influence of RH on aerosol particle size for respirators has been reported (Mahdavi et al., 2014). The data from the study showed an increase of larger size particles with a decrease in smaller size particles at higher than 50% RH. The most penetrating particle size showed a shift of ~20 nm toward larger sizes at higher RH. The SWPF results obtained in Study 2 decreased with particle sizes from 10 to 400 nm size range and showed no particle size dependency for all types of respirators. This indicates that the growth of particles to larger sizes at higher RH may not explain the SWPF results obtained in the study.

Some studies on WPF showed no particle size dependency (Bidwell and Janssen, 2004; Janssen et al., 2007; Janssen and McCullough, 2010). This can be explained by a closer look at the particle size distribution in those workplaces. The workplaces above showed a particle size distribution of approximately ~5 μm mass median aerodynamic diameter (MMAD). In these studies, the distribution of relatively larger size range particles contributed to the TIL (inverse function of respiratory protection) measured for respirators. One study measured TIL for N95 FFRs worn by human subjects as well as a manikin head form (Grinshpun et al., 2009). Their results showed that both filter media penetration and face seal leakage were higher at ~100 nm (aerodynamic diameter) and decreased with increasing particle sizes. The results are supported by the decrease in the TIL measured with increasing particle sizes from 50 nm up to 800 nm size particles using a breathing manikin head form (Rengasamy and Eimer, 2012). The above results suggest that TIL values would be much smaller for particles in the larger size range (~3–10 μm). Smaller TIL or larger SWPF values are expected to show only a weak or no relationship between particle size and WPF described in some studies (Bidwell and Janssen, 2004; Janssen et al., 2007; Janssen and McCullough, 2010). Moreover, measuring the concentration of larger size particles inside the respirator has potential problems as reported in previous studies (Janssen and Bidwell, 2007; Janssen et al., 2007).

Despite the difference between Study 1 and Study 2 results, the two studies showed some similarities. Both studies showed the influence of filter efficiency of respirators on SWPF values. Study 1 showed relatively higher filter efficiency for one of four N95 FFR models tested for filtration performance (Rengasamy et al., 2013). The higher efficiency model was found to produce larger GM SWPF and fifth percentile values in the two test laboratories. The three less efficient models showed relatively lower GM SWPF and fifth percentile values (Rengasamy et al., 2014). Interestingly, the data from Study 2 also showed filter efficiency dependency of SWPF values. The relatively higher efficiency P100 FFR models tested in the study showed larger GM SWPF and fifth percentile values than the two lower efficiency N95 FFR models. Similarly, higher efficiency P100 filters of EHRs showed larger GM SWPF and fifth percentile values than the two N95 filters of EHRs. The larger SWPFs for higher efficiency respirators obtained in our studies can be explained by the smaller TIL obtained using test subjects (Frost et al., 2014; Rengasamy et al., 2013) and a manikin (Rengasamy and Eimer 2012).

21.5 Conclusions

Study 1 results showed that the SWPFs and fifth percentile SWPFs for two N95 FFR models were smaller in Laboratory 1 for aerosol with a mean CMD of 82 nm than in Laboratory 2 with a CMD of 131 nm showing a relationship between particle size distribution and SWPF values. The results indicate that smaller SWPFs and fifth percentile values can be expected for particle size distributions within the nanoparticle size range (<100 nm). Results from Study 2 showed that the SWPF and fifth percentile values decreased with increasing particle sizes from 10 to 400 nm for FFRs and EHRs. Filter efficiency appears to influence the SWPF and fifth percentile values. The SWPF results obtained in our studies indicate that NIOSH-approved respirators would provide expected levels of protection for nanoparticles. Further studies on the relationship between particle size distribution and SWPS, and particle size growth during human breathing conditions are needed to understand respiratory protection from nanoparticles.

Acknowledgments

The authors acknowledge NIOSH colleagues Zhipeng Liu, George Niezgoda, Matthew Horvatin, and Margaret Sietsema for their useful suggestions and critical review of the manuscript. This research work was supported by NIOSH funding. The authors declare there are no conflicts of interest in relation to this paper.

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22

An ab initio Approach for Modeling Respirator Penetration Distribution

Ziv Klausner and Eyal Fattal

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22.1 Introduction

Many natural phenomena are modeled using random variables, and as such are described via probabilistic distributions. Quite often this description is based on an assumed parametric distribution. This assumption is supported by the statistical fit of various data sets to this distribution. Such methodology lack generality and lead to various problems. One of these is a random variable that is associated by several assumed probability distributions, each of which is backed by fit to several datasets. Examples to this are the probability distribution of wind speed in a given location over a certain period of time, which is described in the literature by either Weibull, lognormal, or Rayleigh distributions (Celik, 2004; Garcia et al., 1998; Jamil et al., 1995); and earthquake recurrence time interval which is described by either lognormal, gamma, or Weibull distributions (Matthews et al., 2002). A different problem is when the assumed distribution's range does not overlap the range of the random variable. This is the case when penetration of a contaminant into a respirator, which is physically bound between 0 and 1 is described by lognormal distribution, which is defined on the range 0 to infinity (Nicas, 1994). Another example is earthquakes recurrence time, which can only be positive, is modeled by the Gaussian distribution, which assigns positive probability to negative values (Matthews et al., 2002).

Contrary to assumptions based on statistical fit, there are natural phenomena where the modeling of the random variable has a theoretical basis from physical ab initio considerations. Examples for such variables are the velocity of molecules of gas in equilibrium which is distributed according to the Maxwell–Boltzmann distribution (Bricmont et al., 2001); particle size in naturally occurring aggregates which follows the lognormal distribution (Halmos, 1944; Johnson and Kotz, 1970); the velocity of a stationary and isotropic turbulent fluid which follows the Gaussian distribution (Tessarotto and Asci, 2010) as well as the concentration of a contaminant emitted from a continuous point source into a unidirectional wind blowing in a domain of infinite extent (Stockie, 2011).

The abovementioned ab initio studies serve as motivation to the present work, which focuses on the process of respiratory protection. Our aim is to develop a physical formulation of this process from first principles. In this chapter, which is based on our paper (Klausner and Fattal, 2014), we show that an ab initio formulation leads to a stochastic differential equation whose solution is the probability density functions of the beta distribution. Examination using data of many respiratory protection experiments showed that indeed the beta distribution fits the data better than the commonly assumed lognormal distribution. As an outcome of these findings, a new theoretical framework is suggested for modeling respiratory protection (Section 22.2) and then applied to different datasets (Section 22.3).

22.2 Method

22.2.1 Definitions

Generally speaking, the purpose of a respirator is to lessen the inhalation exposure to a contaminated environment. Therefore, the level of respiratory protection is a measure of the proportion of the contaminant concentration that penetrates the respirator. The *penetration*, *P*, is defined according to Equation 22.1:

$$P \equiv \frac{C_i}{C_o} \tag{22.1}$$

where C_o is the concentration of ambient contaminant and C_i is the concentration of contaminant inside the respirator (C_i is also referred sometimes as the penetration concentration and C_o is referred as the exposure concentration). The penetration, P, is a dimensionless measure, not dependent on the measuring units of the concentrations. The possible values of penetration are within the interval [0, 1], where $P = 0$ means perfect protection while $P = 1$ means that the respirator totally malfunctioned.

Occasionally it is convenient to use the reciprocal of the penetration, the *protection factor,* defined as Equation 22.2:

$$PF \equiv \frac{1}{P} \Rightarrow \frac{C_o}{C_i} \tag{22.2}$$

22.2.2 Formulation of the Kinetic Differential Equation (the Deterministic Part)

We begin with formulating the general problem of the rate of change in time of a gas concentration, C_t, within a given volume, V. C_t is normalized by the gas' saturation concentration. Let there be a gaseous contaminant source outside V, whose normalized generation rate is G. If f is the fraction of G that enters V, then fG is the rate at which the contaminant enters the volume. V is ventilated at a rate of Q, so part of the contaminant mass leaves V.

This problem can be formulated using the differential equation (Equation 22.3):

$$\frac{dC_t}{dt} = \frac{fG - QC_t}{V} \tag{22.3}$$

Equation 22.3 may be considered as describing C_i, the concentration of the contaminant in the air inside the respirator. In this case Q refers to the breathing rate in units of volume per unit of time. Assuming that V, the volume within the respirator, is well mixed, we rewrite Equation 22.3 as Equation 22.4:

$$\frac{dC_{i_t}}{dt} = \frac{Q}{V}\left(\frac{fG}{Q} - C_{i_t}\right) \tag{22.4}$$

Equation 22.4 is a one-dimensional kinetic equation, of the type $\frac{dC_{i_t}}{dt} = a(C_{i_t})$, where $a(C_{i_t})$ is often referred to as the drift term (Risken, 1989).

22.2.3 The Stochastic Approach and an Analytical Solution

Equation 22.4 is a deterministic differential equation. Thence when the values of all the variables are explicitly known and given appropriate initial conditions, it has a single solution. This kind of solution is limited because it assumes that there is complete assurance in the value of the equation's solution. An alternative approach is to account for uncertainties by describing the problem as a stochastic process. This approach has been successfully applied to many physical systems (Van Kampen, 2003). According to this approach, C_i will be regarded as a random (or stochastic) variable. In this scenario, Equation 22.4 should be transformed into a one-dimensional generalized Langevin (GL) *stochastic differential equation* (SDE) (Equation 22.5):

$$dC_{i_t} = a\left(C_{i_t}\right)dt + b\left(C_{i_t}\right)dw_t \tag{22.5}$$

where $a\left(C_{i_t}\right)$ is the kinetic deterministic term from above and $b\left(C_{i_t}\right)$ is the diffusive term which will be discussed later. These terms are the first- and second-order Kramers–Moyal coefficients, respectively (Risken, 1989). w_t is a standard Wiener process, that is, delta correlated Gaussian white noise. Since Equation 22.5 represents a single instance, a solution for this equation involves representation of an ensemble, that is, computing the averaged behavior of a large number of realizations.

An equivalent representation to the Langevin equation is the Fokker–Planck (FP) equation which is an equation for the *probability density function* (PDF; (Risken, 1989)) (Equation 22.6). It should be noted that this equivalence is important mainly as a tool for determining the $a\left(C_{i_t}\right)$ and $b\left(C_{i_t}\right)$ terms, when they are unknown.

$$\frac{\partial f}{\partial t} = \frac{\partial[a(C_i)f(C_i,t)]}{\partial C_i} + \frac{\partial^2[b^2(C_i)f(C_i,t)]}{\partial C_i^{\,2}} \tag{22.6}$$

where $f(C_i, t)$ is the PDF. Now it is also clear why $b\left(C_{i_t}\right)$ is referred as the diffusion term.

If we solve this FP equation for steady state, that is, $\frac{\partial f}{\partial t} = 0$ we get the solution (Equation 22.7):

$$f(C_i) = \frac{\psi}{b^2}\exp\left[\int_{-\infty}^{S}\frac{a(s)}{b^2(s)}ds\right] \tag{22.7}$$

where the constant ψ is chosen so $\int_{-\infty}^{+\infty} f(C_i)dC_i = 1$.

The solution to Equation 22.5 depends on the principal form of the diffusion term $b(C_i)$. In our case we use the following principal form (Cobb, 1981; Cobb et al., 1983) (Equation 22.8):

$$b^2(C_i) = \varepsilon C_i(1 - C_i) \tag{22.8}$$

where ε is a constant ($\varepsilon = 2fGQ/V^2$, see Section 22.2.4).

Using the specified $a(C_{i_t})$ and $b(C_{i_t})$ the explicit equation for C_{i_t} becomes Equation 22.9:

$$dC_{i_t} = \frac{Q}{V}\left(\frac{fG}{Q} - C_{i_t}\right)dt + \sqrt{\varepsilon C_{i_t}(1 - C_{i_t})}dw_t \tag{22.9}$$

The stationary solution for Equation 22.9 is the PDF of the standard beta distribution (Cobb, 1981; Cobb et al., 1983) (Equation 22.10):

$$f(c) = \frac{\Gamma(p+q)}{\Gamma(p)\Gamma(q)} c^{p-1}(1-c)^{q-1} \tag{22.10}$$

where c is some value of C_i, $\Gamma(\alpha)$, is the gamma function with argument α; for example, (Press et al., 1986) and p and q are defined as Equations 22.11 and 22.12:

$$p = \frac{fG}{Q\delta} \tag{22.11}$$

$$q = \frac{Q - fG}{Q\delta} \tag{22.12}$$

where δ is defined as Equation 22.13:

$$\delta = \frac{1}{p+q} = \frac{\varepsilon V}{Q} \tag{22.13}$$

22.2.4 Analysis of the SDE

In order that the SDE described in Equation 22.9 will have a solution and this solution will be unique the following conditions are required (Gardiner, 1997):

1. Lipschitz condition: a K exits such that (Equation 22.14):

$$\left|\frac{Q}{V}\left(\frac{fG}{Q} - x_t\right) - \frac{Q}{V}\left(\frac{fG}{Q} - y_t\right)\right| + \left|\sqrt{\varepsilon x_t(1-x_t)} - \sqrt{\varepsilon y_t(1-y_t)}\right| \le K \mid x_t - y_t \mid \tag{22.14}$$

   for all x_t and y_t and all t in the range $[t_0, T]$.

2. Growth condition: a K exists such that for all t in the range $[t_0, T]$ (Equation 22.15),

$$\left|\frac{Q}{V}\left(\frac{fG}{Q}-x_t\right)\right|^2+\left|\sqrt{\varepsilon x_t(1-x_t)}\right|^2 \leq K^2\left(1+|x_t|^2\right) \tag{22.15}$$

In the following sections of this section the inequalities will be further developed with the purpose of showing that these conditions are satisfied.

22.2.4.1 The Lipschitz Condition

The inequality in Equation 22.14 can be separated into two inequalities, one for the kinetic deterministic term (Equation 22.16) and the other for the diffusive term (Equation 22.17):

$$\left|\frac{Q}{V}\left(\frac{fG}{Q}-x_t\right)-\frac{Q}{V}\left(\frac{fG}{Q}-y_t\right)\right| \leq A\,|x_t-y_t| \tag{22.16}$$

$$\left|\sqrt{\varepsilon x_t(1-x_t)}-\sqrt{\varepsilon y_t(1-y_t)}\right| \leq B\,|x_t-y_t| \tag{22.17}$$

where $K = A + B$.

22.2.4.1.1 The Deterministic Term

First, the brackets in Equation 22.16 are removed which leads to a simpler expression (Equation 22.18):

$$\left|-\frac{Q}{V}(x_t-y_t)\right| \leq A\,|x_t-y_t| \tag{22.18}$$

Now, because Q, the breathing rate and V, the volume within the respirator are both nonzero and positive numbers $\left|-\frac{Q}{V}\right|=\frac{Q}{V}$. This allows the removal of this ratio outside the absolute bars so Equation 22.18 can be written as Equation 22.19:

$$\frac{Q}{V}\,|(x_t-y_t)| \leq A\,|x_t-y_t| \tag{22.19}$$

This inequality holds for every $A \geq \frac{Q}{V} > 0$.

22.2.4.1.2 The Diffusive Term

The domain of Equation 22.17 is all $x_t, y_t \in [0, 1]$. Because x_t and y_t are actually gas concentrations normalized by the saturation concentration, every physically possible x_t and y_t are within this range.

When $x_t = 0$ and $y_t = 1$ (or the other way round, $x_t = 1$ and $y_t = 0$), the right-hand side of Equation 22.17 equals zero, and the left-hand side equals B. In that case, Equation 22.17 is satisfied for every $B \geq 0$.

Whenever $x_t = y_t$ Equation 22.17 is satisfied as equality in which both sides are equal to zero. In this case, B can be any value, and specifically every $B \geq 0$.

Now the case where $x_t > y_t$ and $0 \leq x_t, \ y_t \leq 1$ will be discussed. Because $x_t - y_t > 0$, $|x_t - y_t| = x_t - y_t$. Moreover, $\left|\sqrt{x_t(1-x_t)} - \sqrt{y_t(1-y_t)}\right| = \sqrt{x_t(1-x_t)} - \sqrt{y_t(1-y_t)}$. Therefore, the absolute bars in Equation 22.17 can be removed and a simplified expression is resulted in Equation 22.20:

$$\sqrt{x_t - x_t^2} - \sqrt{y_t - y_t^2} \leq \frac{B}{\sqrt{\varepsilon}}(x_t - y_t) \tag{22.20}$$

For every x_t, y_t in the given range $x_t \geq x_t^2, y_t \geq y_t^2$, and also $x_t \geq \sqrt{x_t}, y_t \geq \sqrt{y_t}$. Accordingly (Equation 22.21),

$$\sqrt{x_t - x_t{}^2} - \sqrt{y_t - y_t{}^2} \leq \sqrt{x_t} - \sqrt{y_t} \leq (x_t - y_t) \tag{22.21}$$

From Equation 22.21, it is concluded that Equation 22.20 is satisfied for every $B \geq \sqrt{\varepsilon}$.

When $x_t < y_t$, an inequality similar to Equation 22.20 results, where the only difference is that x_t is replaced by y_t and vice versa. The conclusion is similar, the inequality is satisfied for every $B \geq \sqrt{\varepsilon}$.

The above analysis has shown that the Lipschitz condition is satisfied for both the deterministic and diffusive term, for all x_t and y_t and all t in the range $[t_0, T]$.

22.2.4.2 Growth Condition

First, the absolute bars in Equation 22.15 can be removed because for every $a \in \Re \, | \, a \, |^2 = a^2$. Then, the brackets can be removed leading to the following simpler expression (Equation 22.22):

$$\left(\frac{Q^2}{V^2} - \varepsilon\right)x_t^2 + \left(\varepsilon - \frac{2fGQ}{V^2}\right)x_t + \frac{f^2G^2}{V^2} \leq K^2x_t^2 + K^2 \tag{22.22}$$

Because both sides on Equation 22.22 are second degree polynomials, in order to satisfy the inequality the following conditions on the polynomials' coefficients should be met (Equations 22.23 through 22.25):

$$\frac{Q^2}{V^2} - \varepsilon \leq K^2 \tag{22.23}$$

$$\varepsilon - \frac{2fGQ}{V^2} = 0 \tag{22.24}$$

$$\frac{f^2G^2}{V^2} \leq K^2 \tag{22.25}$$

Equation 22.24 leads to a requirement on the value of ε (Equation 22.26):

$$\varepsilon = \frac{2fGQ}{V^2} \tag{22.26}$$

It should be noted that because the diffusion term in Equation 22.9 is a square root, ε is required to be any positive value. In the case of the ε in Equation 22.26, due to the fact that in any physically plausible scenario all the parameters are positive, $\varepsilon > 0$. However, the meaning of Equation 22.26 is that in order to satisfy the growth condition, and thus assure the existence and uniqueness of a solution to Equation 22.9, a specific value for ε is required.

Regarding Equations 22.23 and 22.25, adding these, while the value of ε from Equation 22.26 is substituted, result in the following inequality (Equation 22.27):

$$\frac{Q^2}{V^2} - \frac{2fGQ}{V^2} + \frac{f^2G^2}{V^2} \leq 2K^2 \tag{22.27}$$

By using the binomial theorem, Equation 22.27 can be rewritten as Equation 22.28:

$$\frac{1}{2}\left(\frac{Q}{V} - \frac{fG}{V}\right)^2 \leq K^2 \tag{22.28}$$

This leads to Equation 22.29:

$$\frac{1}{2}\left|\frac{Q}{V} - \frac{fG}{V}\right| \leq K \tag{22.29}$$

Therefore, any K that follows the requirement in Equation 22.29 satisfies the growth condition in Equation 22.15. Therefore the existence of a K that satisfies the growth condition was proved. This leads the analysis to a conclusion that because the SDE in Equation 22.9 satisfies the Lipschitz and growth conditions, a solution for it exists and it is unique.

22.2.5 Equivalence of the Distribution of *P* to the Distribution of C_i

Contrary to the fact that C_i is a random variable, it can be argued that C_o, the concentration of contaminant in the air outside the respirator, can be well considered a constant. It is obvious in controlled surroundings, such as in a test chamber during a respiratory protection experiment, that C_o is kept constant. However, even in an atmospheric environment, C_o may be considered as constant due to a slower rate of change in comparison to the scale of change of C_i (i.e., the adiabatic assumption). Now, with a C_i, which is a beta distributed random variable, and a constant C_o, we can now get back to *P*, the ratio of C_i to C_o by the following proof.

Theorem: If $C_i \sim$ *beta* then $P \sim$ *beta*

Proof (Equation 22.30):

$$F_{C_i}(c_i) = \Pr\{C_i < c_i\} = \Pr\{C_o \cdot P < c_i\} = \Pr\left\{P < \frac{c_i}{C_o}\right\} = F_P\left(\frac{c_i}{C_o}\right) \tag{22.30}$$

where $F_X(x)$ is the *cumulative distribution function* (CDF) of a random variable *X*, which is defined as: $F_X(x) = \int_{-\infty}^{x} f(t)dt = \Pr\{X < x\}$. Note that the equality $C_i = C_o \cdot P$ follows from the definition of *P* (Equation 22.1).

It was shown, based on first principles, that *P* is beta distributed. From here, it is then appropriate to use the beta distribution to model respiratory penetration.

22.3 Application

In the previous section we have showed that based on first principles the beta distribution proposes a new theoretical framework for modeling respiratory protection. In this section we analyze the data of several respiratory protection experiments in order to test this theoretical conclusion. The problem at hand is to figure out whether experimental data follow a given distribution in general, regardless of the specific values of the distribution's parameters of a given dataset. In such problems the customary approach is to examine whether the higher moments of the experimental distribution follow the expected theoretical relationships (Chatwin et al., 1995; Mole and Clarke, 1995). Following this approach we examine a large number of penetration distributions measured in different experiments and analyze their third and fourth moments, namely kurtosis and skewness. We treat these as coordinates in the kurtosis–skewness plane and compare these to the theoretic curves associated with the different shape parameters of the lognormal and beta distributions. The lognormal distribution is mentioned here as it is commonly assumed that penetration measurements follow the lognormal distribution (Hu et al., 2016; Nicas and Neuhaus, 2004).

The central moments of the *probability density function* (PDF) of a random variable contain important properties of this variable. Such properties include the random variable's identification as a member of a family of distributions and even the shape of the PDF (Johnson and Kotz, 1970). The n-th central moment ($n \geq 2$), μ_n is defined as Equation 22.31:

$$\mu_n = E[(P-\mu)^n] = \int_{-\infty}^{+\infty} (p-\mu)^n \cdot f(p)dp \tag{22.31}$$

where P is the penetration random variable, μ is the mean, p is some value of $P, f(p)$ is the PDF. It should be noted that the second central moment, μ_2, is the variance of P and usually denoted by σ^2 (Johnson and Kotz, 1969).

Since the value of μ_n is in units of power of n (e.g., μ_3, is in "cubed" units) it is useful to employ dimensionless statistics to express the third and fourth moments, skewness, S, and kurtosis, K, respectively (Equation 22.32):

$$S = \frac{\mu_3}{\sigma^3}, K = \frac{\mu_4}{\sigma^4} \tag{22.32}$$

Given samples from a population, the sample skewness, $\hat{S}$, and sample kurtosis, $\hat{K}$, are estimators to the population skewness and kurtosis, S and K, respectively (Sheskin, 2000) (Equation 22.33):

$$\begin{aligned} \hat{S} &= \frac{\frac{1}{n}\sum_{i=1}^{n}(x_i-\bar{X})^3}{[Var(X)]^{3/2}} \\ \hat{K} &= \frac{\frac{1}{n}\sum_{i=1}^{n}(x_i-\bar{X})^4}{[Var(X)]^2} \end{aligned} \tag{22.33}$$

where n is the sample size of the random variable X, x_i is the i-th sample. $\bar{X}$ and $Var(X)$ are the sample mean and variance, respectively (Equation 22.34):

$$\begin{aligned} \bar{X} &= \frac{1}{n}\sum_{i=1}^{n} x_i \\ Var(X) &= \frac{1}{n}\sum_{i=1}^{n}(x_i-\bar{X})^2 \end{aligned} \tag{22.34}$$

In several families of distributions there is an approximated theoretical relationship between K and S. This relationship occurs in any distribution within these families, regardless of the exact distribution parameters.

Regarding the family of the lognormal distributions, we note two such relationships, dependent on the value of σ_g, the geometric standard deviation (Mole and Clarke, 1995) (Equation 22.35):

$$\begin{aligned} &K \approx \frac{16}{9}S^2 + 3 \qquad \text{if } \sigma_g < e \\ &K \approx S^{8/3} \qquad\qquad \text{if } \sigma_g > e \end{aligned} \tag{22.35}$$

For the family of the beta distributions the different shapes of the distribution dictate the relationship between K and S. Regarding the U- and J-shaped beta distributions the relationships are (Chatwin et al., 1995) (Equation 22.36):

$$\begin{aligned} &K \approx S^2 + 1 \qquad \text{for a U-shaped distribution} \\ &K \approx \frac{3}{2}S^2 \qquad\quad \text{for a J-shaped distribution} \end{aligned} \tag{22.36}$$

The penetration data analyzed consisted of a group of 54 datasets of respiratory protection measurements. Twenty-seven of these were measured in the Israel Institute for Biological Research (IIBR) laboratory and consisted of 21 gas masks and six personal hoods datasets. The second half of the datasets group was a collection of measurements from the literature which involved several types of respirators: nine datasets of filtering facepieces (Bidwell et al., 2004; Han, 2002; Janssen et al., 2007a,b), nine datasets of half facepieces (Janssen and McCullough, 2010; Myers et al., 1996; Myers and Zhuang, 1998; Weber and Mullins, 2000; Zhuang et al., 2003; Zhuang and Myers, 1996), seven datasets of gas masks (Busmundrud, 1998; Cohen, 1999), and two datasets of escape hoods (Campbell and Seiple, 2004). The challenge agent which was used to quantify the respirators performance varied among the datasets. In order to measure respirators' fit the following agents were used: corn oil aerosol ((Campbell and Seiple, 2004; Cohen, 1999); IIBR measurements), sodium chloride aerosol (Busmundrud, 1998), and particles in the ambient air (Han, 2002; Zhuang et al., 2003). When respirators' field performance was evaluated several agents were measured. Most studies dealt with the challenge of iron (Han, 2002; Janssen et al., 2007a; Myers and Zhuang, 1998; Zhuang et al., 2003), lead (Janssen and McCullough, 2010; Myers et al., 1996), and calcium (Bidwell et al., 2004; Myers and Zhuang, 1998). Other agents were zinc (Myers et al., 1996), chromium and titanium (Zhuang and Myers, 1996), styrene (Weber and Mullins, 2000), magnesium and aluminum (Janssen et al., 2007b), and silicon (Bidwell et al., 2004).

Figure 22.1 shows the sample kurtosis $\hat{K}$ plotted against the sample skewness $\hat{S}$ of the 54 datasets. Each $(\hat{S}, \hat{K})$ point represents a different experiment.

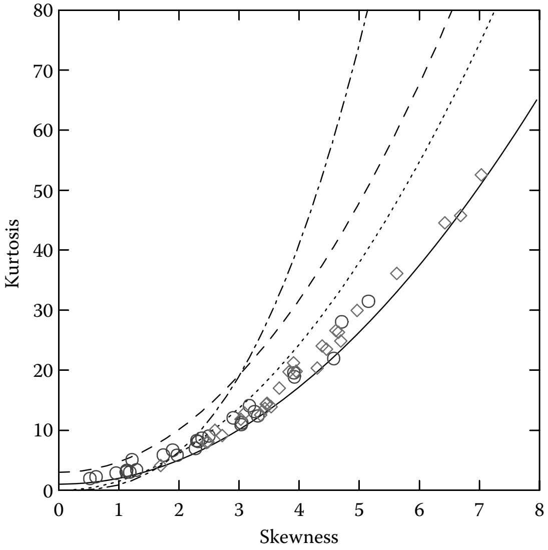

FIGURE 22.1
The relationship between kurtosis and skewness for 54 respiratory protection datasets. Of these, measurements performed in the IIBR laboratory are represented by diamonds and measurements from the literature are represented by circles. The theoretical relationship for U- and J-shaped beta distributions are represented by a solid and a dotted line, respectively. The theoretical relationship for a lognormal distribution with $\sigma_g < e$ and $\sigma_g > e$ is represented by a dashed line and a dashed-dotted line, respectively.

Some of the experiments involved the same respirator, each time examined in different conditions. For example Busmundrud (1998) examined three types of respirator, each tested as received from the factory and then after it had undergone field use. Figure 22.1 also includes the curves of the K and S relationships for the lognormal and beta distributions described in Equations 22.35 and 22.36.

The collapse of the data to the beta distribution curves shown in Figure 22.1 is remarkable. Moreover, the majority of the $(\hat{S}, \hat{K})$ points are closer to the K–S relationship curve of the U-shaped beta distribution rather than the curve representing the J-shaped distribution. A U-shaped distribution can suggest a two-state process (i.e., the weighted sum of two delta functions; Chatwin et al., 1995). Regarding respiratory protection, this shape might indicate that the population of respirator users is composed of two subpopulations. One subpopulation is protected exceptionally well by the respirator, while the other is poorly protected.

Contrary to the beta distribution, the lognormal distribution clearly provides a very poor fit without any regard to the value of σ_g. Note that if the data were derived from the normal distribution all data points would have been around a single point in the S–K plane, at $(S, K) = (0, 3)$. Similar results would have been found if the data were derived from the exponential distribution, but all points would have been around the point (S, K) = (2, 9) (Mole and Clarke, 1995). It is clear that these distributions do not describe the data as most of the results are far from these points.

Another deficiency of the lognormal distribution is attributed to its being defined on values from zero to positive infinity, whereas penetration values are physically bounded between zero and one. Hence there are scenarios in which the lognormal distribution evaluates the possibility of penetration values beyond the physical upper limit of one by a considerable probability (Nicas, 1994). This drawback cannot occur in the beta distribution in that one of its characteristics is its restricted range. For penetration values, this range is typically the interval [0,1].

22.4 Conclusions

We have presented in this work a new theoretical framework for modeling respiratory protection. It was shown, based on first principles analytical arguments and on comparison to measurements, that the penetration of a contaminant concentration into respiratory protection equipment is beta distributed.

This new framework can improve the design of experiments by allowing the sample distribution of any statistic of interest to be derived from the appropriate analytic distribution for penetration, the beta distribution. It may also be used to calculate a more precise estimate for the penetration percentiles in the population. These estimates usually serve as criteria for accepting or rejecting respirator systems.

Acknowledgments

The authors gratefully acknowledge the contribution of Dr. Yehudah Alexander and Dr. Shai Kendler for fruitful and helpful discussions regarding this study.

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23

Improving Respirator Filter Formulations through Combinatorial Science

Jennifer V. Romero and Jeff R. Dahn

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23.1 Introduction

The current trend in the manufacture of respiratory protective equipment (RPE), more specifically of respirator filter cartridges is a move toward lowering the burden of use on the wearer. One approach is to decrease the breathing resistance through a respirator filter by decreasing the amount of adsorbent used in the manufacture of filter cartridges. In order to achieve this, new and improved impregnated activated carbon (IAC) recipes must be found. Ideally, the new adsorbent formulation should have an increased adsorption capacity for a specific set of toxic gases at lower carbon bed volumes.

IAC has always been the preferred material to use in respirator filters for the adsorption of a broad range of toxic gases (Bansal and Goyal 2005, Fortier et al. 2008). Activated carbon by itself only effectively adsorbs impurities such as organic vapors within its large network of channels and pores. Untreated, activated carbon fails to adsorb low molecular weight, highly polar gases. Many gases used in either industry or chemical warfare fall into this category and are not readily removed by activated carbon alone. Chemical treatments or impregnation must be made on the activated carbon. Such treatment or impregnation on the carbon serve to either neutralize or transform the toxic chemical into nontoxic gases that are readily adsorbed by the carbon or is rendered safe to release in the environment. Traditional formulations for impregnated carbon use copper and/or zinc-based reagents which are solubilized in an ammonia containing solvents (Doughty and Groose 1991, Doughty et al. 1996). Such recipes have not changed in recent years, and the need for new adsorbent formulations is increasing. In addition, the use of ammonia as a solubilizing agent in the traditional recipe is considered nonideal because of cost and environmental concerns.

The possibility of using other non-carbon materials as filter adsorbents is growing steadily albeit at a slow pace. While such materials have exhibited some ability to adsorb both sulfur dioxide (SO_2) and ammonia (NH_3) gases, it is undeniable that in order to be truly a "multi-gas" adsorbent, it needs to effectively and simultaneously be able to capture various organic vapors within their pores. This is the best feature of IAC in addition to its low cost of production, and its use as a multipurpose respirator filter adsorbent medium is still very much widely preferred.

To successfully improve the IAC adsorbent formulation, it is important to find an optimum set of impregnants which do not require solubilization in aqueous ammonia, are preferably water based due to environmental concerns, and that apply to an activated carbon so that a specific broad range set of toxic gases can be effectively adsorbed. However, finding the right combination of impregnants to prepare optimum IACs can be time consuming. The combinatorial strategy has been adapted for the preparation and screening of many different IACs simultaneously (Romero et al. 2010). Formulations with various combinations of up to four (or more) metallic and organic components can be studied and evaluated quickly for their ability to adsorb a wide variety of toxic gases through combinatorial methods.

Comparison of the combinatorially prepared IACs with benchmark multigas adsorbents enabled the rapid identification of viable adsorbent formulations. The adsorption capacity of the impregnated carbon is calculated gravimetrically from the increase in the mass of the exposed adsorbent.

Formulations with a high adsorption capacity were chosen and were deemed viable. In addition, x-ray powder diffraction was used to identify the impregnant phase(s) present in each sample which allowed for a correlation between the identity of the impregnant(s) and gas adsorption performance to be made. From the combinatorial studies, viable gas adsorbent materials with different compositions were prepared on a larger scale and tested for multi-gas respirator capacities using mock industrial flow tests.

23.1.1 Combinatorial Materials Preparation

Joseph Hanak pioneered the use of combinatorial science (combi) for the preparation and screening of numerous materials simultaneously in the 1970s (Hanak 1970, 2003, Xiang et al. 1995). Since then, similar strategies were used to explore and prepare advanced materials such as composition-spread thin films to be screened in battery, fuel cell, and biomaterials applications (Rockwell et al. 2007, Easton et al. 2008, Li et al. 2008, Liao et al. 2008). Others have used the combinatorial approach to generate libraries of materials for catalysis, high temperature superconductivity, ferroelectricity, and other applications (Schultz and Xiang 1998, Evans et al. 2001, Reichenbach et al. 2003, Koinuma and Takeuchi 2004, Olong et al. 2007). Most notable is the use of the same combinatorial technique in the study of pseudo-ternary Li–Mn–Ni oxide as positive electrode materials in Li–ion battery applications (McCalla and Dahn 2013).

IACs were prepared with the aid of a solutions handling robot (Figure 23.1a) in this combi method. Arrays of up to 100 samples were prepared by dispensing varying amounts of two (or more) solution components on a shallow bed of activated carbon held in tiny vials (Figure 23.1b). Up to five arrays of samples can be prepared by the solutions handling robot at one time. A series of thermal decomposition steps under inert atmosphere was employed to decompose the impregnants to the desired active phases.

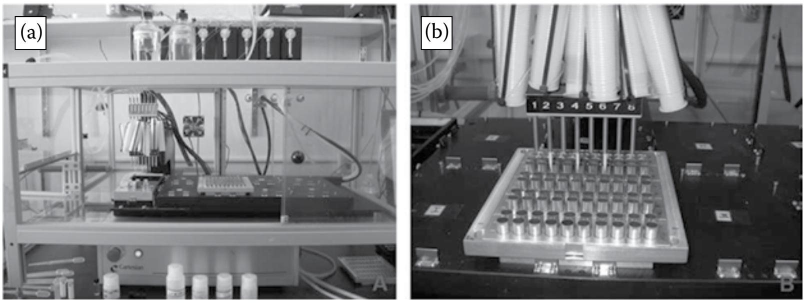

FIGURE 23.1
(a) A photo of the solutions handling robot and (b) an array of samples containing 80 vials is shown here being dispensed with impregnants using the robot.

The analysis of the gas adsorption performance of the samples was done gravimetrically. The adsorption capacity (mmol gas/g AC) of each sample was calculated from the difference of the masses before and after gas exposure as shown in Equation 23.1

$$\text{Gas adsorption capacity} = \frac{(\text{mass of } IAC_{before} - \text{mass of } IAC_{after}) / \text{molar mass gas}}{\text{Mass of } AC \text{ in mg} * 1000} \tag{23.1}$$

The gas adsorption efficiency (or "stoichiometric reaction ratio" [SRR]) of the material is determined from the ratio of the mmol of gas adsorbed and the total mmol M added, where M is the metal impregnant. The SRR quantifies the material's ability to filter toxic gases. The determination of impregnant phases present was achieved by powder x-ray diffraction (XRD) techniques.

From the results of the combinatorial screening, only a few compositions were chosen for bulk dynamic adsorption studies in order to determine their potential as multi-gas adsorbent material. The choice was based on the relatively "balanced" gas adsorption behavior of the materials for both SO_2 and NH_3 gases, and preference was given to compositions with high SRRs.

The method was proven to be both time and cost effective. Traditional sample preparation and testing takes about 8 h per sample while it only takes about a half hour per sample for the combi method. The combi method also requires only a fraction of the total amount of starting material that is typically used for bulk traditional preparation. This novel method of screening has the advantages of parallel preparation and investigation of a large number of samples at one time, which will increase the rate of discovery of viable multi-gas respirator materials.

23.2 Experimental Method

23.2.1 Equipment

A Cartesian PixSys™ SQ series robot equipped with eight 250 μL automated solution dispensers was used for this study. This robot is capable of handling up to eight solutions at one time and capable of dispensing liquids for up to five arrays of 100 tiny vials. The robot comes with a programming software that allowed the control of the solution dispensers with versatility, ease, and precision. The ease of programming made it possible to vary dispensed volumes from 0 to 250 μL with high precision and accuracy depending on specific needs. The robot also included a dispense deck equipped with a wash and vacuum station to prevent solution and sample contamination.

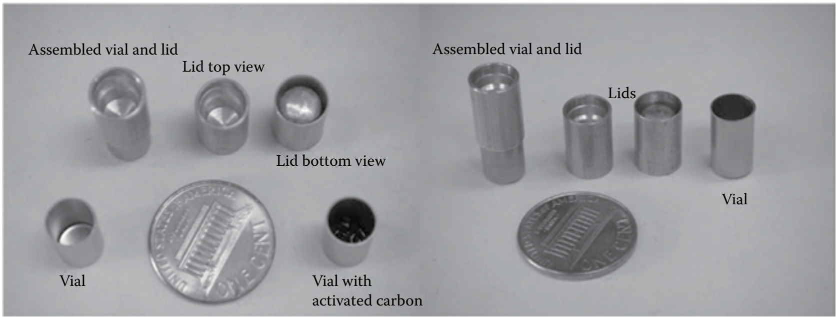

FIGURE 23.2
Photos showing the size of sample holder (vials and lid) relative to a 1 cent coin.

A highly sensitive, precise, and accurate microbalance (Sartorius SE-2) was used to measure mass changes within the sample. The microbalance has the capacity to weigh a maximum of 2.1 g of sample with a resolution of 0.1 μg. Data were automatically recorded onto an Excel spreadsheet using a computer workstation connected to the microbalance.

Gravimetric measurements of activated carbon samples are nontrivial due to their tendency to adsorb moisture rapidly from the air. Therefore, customized tiny sample holders, vials with lids, such as that shown in Figure 23.2, were used to accommodate the limitations in the preparation and weighing of the samples (Romero et al. 2010). These sample holders (vials) needed to be able to withstand heating temperatures of up to 300°C without mass change and deformation. Vials must be conveniently capped and uncapped with tight fitting lids to minimize moisture uptake during weighing. The vials must also be corrosion resistant and must weigh less than 2.1 mg to be compatible for use with the microbalance.

Commercially available stainless steel (grade 304) cylindrical vials with dimensions of 12.7 mm height, 7.1 mm diameter, and a wall thickness of 0.6 mm were obtained from Hudson Technologies. The lids were fabricated in-house from aluminum rods and tubings. The vial and lid together weighed an average of 1.3 g with an approximate volume of 0.3 mL. The customized sample holder was determined to be airtight and satisfied all the requirements stated in the previous paragraph (Romero et al. 2010).

23.2.2 Calibration of the Dispense Program for a 8 × 8 Combi Run

The program used to dispense impregnants with the solutions handling robot was evaluated using 1.34 M zinc sulfate monohydrate ($ZnSO_4{\cdot}H_2O$). Using the robot, increasing increments of $ZnSO_4{\cdot}H_2O$ (Fisher) solution was dispensed into pre-weighed vials using the volumes indicated in Figure 23.3. No activated carbon was used in the vials during calibration.

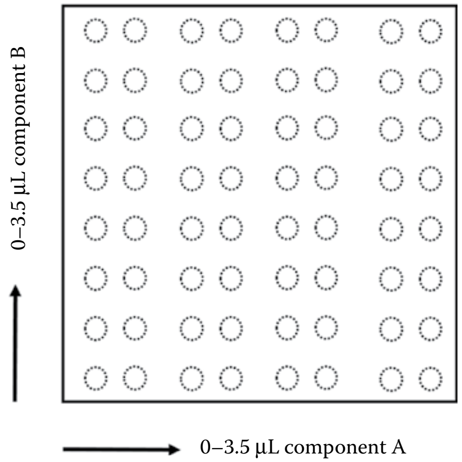
0–3.5 μL component B
0–3.5 μL component A

FIGURE 23.3
Diagram for a typical dispense volume for an 8 × 8 combi array.

23.2.3 Method Validation Using $ZnCl_2$ and K_2CO_3 IACs

Impregnated samples (IACs) for validation were prepared using a modified procedure described in Sections 23.2.2 and 23.2.4. Samples containing 10.0 ± 1.0 mg of pre-dried (120°C air for 2 h) untreated activated carbon was placed into empty, pre-weighed, and dried vials. Appropriate amounts of either 5.0 or 10.0 M $ZnCl_2$ (Sigma) or 1.0 M K_2CO_3 (Aldrich) were dispensed onto the dried activated carbon samples (Romero et al. 2010). Control samples, where no liquids were imbibed, were also prepared in a similar manner using untreated activated carbon. Challenge gas testing of the samples in the vials was performed as described in Section 23.2.5.

23.2.4 Combi Method of Sample Preparation

Figure 23.4 shows a simplified flowchart of the combi method of sample preparation (Romero et al. 2010). A commercially available granular activated carbon derived from coconut shells (AC) with a mesh size of 12 × 35, corresponding to particles between 0.50 and 1.70 mm in diameter, was obtained from Kuraray Chemical Company (Westreich et al. 2007, Fortier et al. 2008,

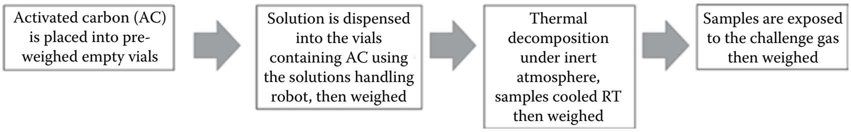
Activated carbon (AC) is placed into pre-weighed empty vials
Solution is dispensed into the vials containing AC using the solutions handling robot, then weighed
Thermal decomposition under inert atmosphere, samples cooled RT then weighed
Samples are exposed to the challenge gas then weighed

FIGURE 23.4
Simplified flowchart of the combi sample preparation method.

Romero et al. 2010). The carbon samples were used either untreated or pretreated with nitric acid prior to the addition of impregnating solutions using the solutions handling robot.

In some trials, the preparation of IAC adsorbents with varying compositions was accomplished by first pretreating a bulk sample of AC with 4.0 M HNO (Fisher) acid by adding 0.8 mL HNO_3/g AC using a method known as the incipient wetness method (Fortier 2007). The acid-treated carbon was dried in air at 140°C for 30 min and then at 180°C for 2 h. The treatment caused a mass increase of about 4.0% for the activated carbon. The resulting product is called HNO_3-treated AC henceforth.

A general method for the preparation of IACs by the combi method is described in Figure 23.4 and is a modified procedure from the literature (Smith 2008). About 10 ± 1 mg of HNO_3-treated AC (or untreated AC) was placed in pre-weighed vials with lids. The vials were previously cleaned and dried at 120°C for 18 h in air prior to use. The AC samples were placed in the vials and then dried in air for 2 h at 120°C. After 2 h, the vials were capped and cooled inside a dessicator containing calcium sulfate dessicant. The mass of the dried samples was measured prior to impregnation. Impregnating solutions were then dispensed onto the carbon samples using a solutions handling robot. To ensure complete imbibing of the impregnating solutions, the samples were capped and then shaken for 5 min. The decomposition of the impregnants on the carbon was typically accomplished by heating the samples at 200°C under inert atmosphere for 2 h, cooled to room temperature, and then weighed. The samples were further dried at 120°C for 4 h to ensure adequate removal of moisture before the exposure to each of the challenge gases. The dried samples were weighed prior to and after exposure of each array of samples to 1000 ppm of challenge gas. The samples were exposed for 4 h at room temperature and approximately 0% RH at a flow rate of 200 standard cubic centimeters per minute (sccm).

In the study, a number of different compounds and combinations were used. Metal nitrates of copper, zinc, manganese, or nickel; metal chlorides such as copper or zinc chloride and their combinations have all been investigated. Various metallic solutions were also used in the study, in addition to metal chlorides and nitrates, metal acetates and sulfates used in the screening of potential gas adsorbing impregnants especially active for the chemisorption of SO_2, NH_3, and HCN gases (Smith 2008). Also typical in most formulations, $H_3PO_4(MoO_3)12{\cdot}25\ H_2O$ Phosphomolybdic Acid (PMA) was added in small amounts and is an important component in the adsorption of other toxic gases such as cyanogen and cyanogen chloride (Smith 2008). The number of samples in an array can vary from 60 to 80 depending on the need for each experiment. Additional unimpregnated AC samples and benchmark commercial multi-gas adsorbents such as the universal respirator carbon (URC, Calgon) were dried and included in the array of samples for comparison and reference.

25.2.5 SO_2 or NH_3 Exposure of Sample Arrays

Exposure to either SO_2 or NH_3 was performed at room temperature and often at very low humidity conditions. Control, untreated samples were exposed simultaneously with IAC samples. Once the IACs were completely dried and the final dry mass had been measured, the caps of the vials were removed. The vials containing the IACs were quickly placed inside an exposure chamber which was connected to a gas stream source that provided a continuous and constant flow of the test gas. The gas used was 1000 ppm of either dry SO_2 or dry NH_3 set at a flow rate of 200 sccm. Concentrated (5000 ppm (v/v)) of either NH_3 (Praxair) or SO_2 (Praxair) gas was diluted with 160 sccm of compressed dry air (Praxair, Ultra High Purity (UHP) grade) at 0% relative humidity to obtain a final concentration of 1000 ppm of challenge gas. All gases used were certified standard grade and contained less than 10 ppm each of CO_2 and H_2O. The flow rates were monitored using rotameters and mass flow controllers. To ensure even challenge gas distribution to all samples in the array, a 12 V battery operated fan was placed on top of the samples (Romero et al. 2010). A bubbler was connected to the exhaust of the chamber and immersed in a scrubbing solution that consisted of approximately 0.1 g KCl (BDH) dissolved in 100 mL of distilled water to verify that the challenge gas was flowing through the chamber. The pH of the scrubbing solution was monitored using a computerized workstation for the duration of the test. Typical exposure time for the samples was 4 h. The mass of each of the samples was measured immediately after the exposure of the impregnated samples to the challenge gases. The adsorption capacities and the stoichiometric ratio of reaction were calculated from the mass difference of the samples before and after gas exposure.

From the results of the combinatorial screening, a few compositions were chosen for bulk dynamic adsorption studies in order to determine their potential as multi-gas adsorbent material. The choice was based on the relatively "balanced" gas adsorption behavior of the materials for both SO_2 and NH_3 gases.

23.2.6 Sample Characterization

To characterize the samples, both control and exposed, thermogravimetric analysis (TGA) and powder XRD techniques were used to determine if the gases were successfully adsorbed onto the carbon and also to determine the identity of the impregnant phases present. Thermal analysis (TGA) was performed using TA Instruments SDT Q600 simultaneous TGA/ Differential Scanning Calorimeter (DSC) from room temperature to about 1000°C. The samples were analyzed under inert atmosphere (argon) in alumina boats and heated to the final temperature with a ramp rate of 10°C/min. X-ray analysis (XRD) was performed using a Rigaku MiniFlex Diffractometer. Measurements were performed at a scan rate of 0.05° per step with a dwell time of 30 s per step and over a scattering angle range of 5–65°, in air and at room temperature. The x-ray source was a copper tube powered at 30 kV and 15 mA. Samples were finely ground prior to analysis using an agate mortar and pestle.

23.2.7 Preparation and Dynamic Adsorption Studies of Bulk IACs

Bulk samples containing impregnants with the preferred compositions identified from the combinatorial screening method were prepared via the "incipient wetness" method where 15.0 g of previously dried (120°C) AC or HNO_3-treated AC was impregnated at a solution to carbon ratio of 0.8 mL/g. Samples were placed in alumina boats and then heated to 200°C for 2 h under argon flow to allow for decomposition and drying. The bulk samples were then characterized by dynamic adsorption flow tests to evaluate their ability to adsorb several classes of toxic gases. The set-up used was similar to that described in Fortier (2007). Commonly used challenges were SO_2, NH_3, C_6H_{12} (0% Relative Humidity (RH)), and C_6H_{12} (80% RH). The results were reported as breakthrough times (BT). In addition to flow tests, the impregnant phases present in the samples were identified by powder XRD.

23.3 Results and Discussion

23.3.1 Combinatorial Screening of IACs

Typically, filters used on RPE are filled with a bed of IAC materials that have varying capabilities of removing different types of toxic gases and vapors. These materials work well for toxic gas and vapor adsorption because of their high surface area and good pore size distribution, and when combined into a filter cartridge, can effectively remove a wide variety of toxic gases at one time. Activated carbons impregnated with metallic impregnants containing Cu and Zn were traditionally used as multi-gas adsorbents and were highly effective in the chemisorption of several classes of low molecular weight toxic gases (Doughty and Groose 1991, Doughty et al. 1996). However, production of these Cu- or Zn-based IACs requires the use of acidic (HNO_3) or basic (NH_4OH) co-impregnants for enhanced impregnant dispersion which gives off toxic by-products during production. Stricter environmental and production regulations constitutes finding better and more affordable respirator adsorbent formulations.

The combi method was used to develop and identify potentially versatile IACs having new compositions. Such novel chemistries should improve over traditional IAC formulations to allow for clean production and the ease and efficiency of respirator use. As a screening tool, the combi method allows for the preparation of a large number of samples in a short amount of time.

In addition, the method only uses about 10.0 mg of activated carbon and 8.0 μL of impregnating solution for each sample which significantly reduced the amount of waste generated during the screening process. The combi approach is simple; put together impregnants that were found to have good gas adsorptions to come up with an adsorbent that will work as well as or better than the traditional Cu-based IAC benchmark product(s).

23.3.1.1 Method Calibration and Validation

The first step to establishing a method that works was to calibrate the dispense volume of the solutions handling robot. A solution of $ZnSO_4{\cdot}H_2O$ was used for calibration and dispensed in pre-weighed vials. The mass of the remaining $ZnSO_4{\cdot}H_2O$ salt after the evaporation of the solvent indicated the dispense precision of the solutions handling robot. Known amounts of the solution were dispensed in increments of 0.5 μL using a program which linearly increased along both the x- and y-directions. The dispensed solution was dried and the mass of the leftover dried salt in the vials was measured. The amount of salt increased as expected and was consistent with the dispensed volumes in the vials. There were only small fluctuations in the measured mass of the remaining salt which suggested that the robot was dispensing solution precisely and accurately as written in the dispense program. This also suggested that variations in mass increase that may be observed in challenged or exposed adsorbents are material related and not from errors made during the dispensing of the impregnant solutions.

To validate the method, previously reported experiments using $ZnCl_2$ and K_2CO_3 were used (Fortier 2007, Fortier et al. 2008, Romero et al. 2010). These substances are known to effectively adsorb NH_3 and SO_2 gas, respectively (Fortier 2007, Fortier et al. 2008). Each of the impregnated samples was exposed to the challenge gas immediately after exposure, and the mass of the dried and treated IACs were obtained.

From the $ZnCl_2$ experiments, NH_3 gas was effectively adsorbed and retained within the adsorbent matrix through a complex formation reaction Equation 23.2. It was determined that the stoichiometric ratio of reaction (SRR) between $ZnCl_2$ and NH_3, defined to be the number of moles of NH_3 adsorbed per mole of $ZnCl_2$ according to Equation 23.2, varied somewhat between samples. The average SRR for the 10.0 M $ZnCl_2$ IAC's was 1.68 ± 0.09 (Romero et al. 2010). This value was close to the reported value of 1.6 ± 0.1 (long dashed line in Figure 23.5) obtained from traditional dynamic flow tests using larger sample sizes as shown in Figure 23.5 (Fortier 2007). In comparison, IACs impregnated with 5.0 M $ZnCl_2$ resulted in a calculated SRR of 1.76 ± 0.06 (Romero et al. 2010). Stoichiometric ratios of reaction of up to 4 mol of NH_3 per $ZnCl_2$ have been previously reported, depending on the NH_3 partial pressure (Yamaguchi 1978). The SRR value obtained is consistent with the complex formation reaction between x mol of NH_3 (where $x \approx 1.7$)

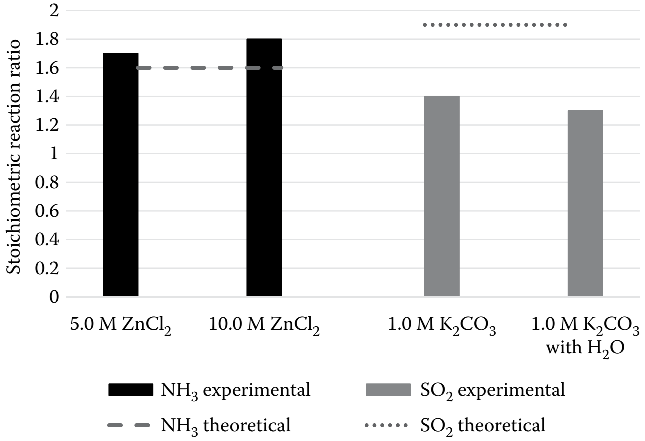

FIGURE 23.5
Comparison of the experimental NH_3 and SO_2 stoichiometric ratios and theoretical or literature SRR values.

and $ZnCl_2$ according to Equation 23.2 (Yamaguchi 1978). Untreated AC control samples showed no significant mass increases when exposed to NH_3 gas. This result is consistent with previous reports of observed low NH_3 gas adsorption capacity for unimpregnated ACs (Yamaguchi 1978, Fortier 2007). Therefore, the mass increase observed for $ZnCl_2$ IAC samples after exposure to dry NH_3 gas can only be attributed to NH_3 gas adsorption.

$$ZnCl_2(s) + x\ NH_3(g) \rightarrow Zn(NH_3)_xCl_2 \tag{23.2}$$

To validate SO_2 adsorption, samples containing K_2CO_3 IACs were used and exposed to dry SO_2 gas. The "retention" of SO_2 gas within the adsorbent is dictated by a single displacement chemical reaction where SO_2 gas reacts with the K_2CO_3 with some adsorbed water in the carbon adsorbent to produce $KHSO_3$ and CO_2 gas as represented by Equation. 23.3 (Fortier 2007)

$$H_2O\ (ads) + K_2CO_3(s) + 2\ SO_2(g) \rightarrow 2\ KHSO_3(s) + CO_2(g) \tag{23.3}$$

It is not clear whether the CO_2 is expelled from the adsorbent or is retained within the micropores of the activated carbon. It is assumed that CO_2 is lost, and therefore a mass increase of only 42 g/mol of SO_2 adsorbed is expected as opposed to the full 64 g/mol.

Unimpregnated activated carbon would inherently adsorb about 0.3–0.4 mmol SO_2/g AC. The addition of the K_2CO_3 onto the AC, increased the material's ability to adsorb SO_2 by slightly more than twice as much as the capacity of the untreated AC. This clearly indicated that the impregnant effectively chemisorbed SO_2, consistent with literature reports (Fortier 2007, Fortier et al. 2007). Figure 23.5 shows that the experimental SRR between SO_2 and K_2CO_3 for IAC's impregnated with only (1.0 M) K_2CO_3 is 1.36 ± 0.12. The SRR is 1.30 ± 0.12 for IAC's impregnated with (1.0 M) K_2CO_3 with some water. Our results were lower than the value of 1.9 ± 0.1 (short dotted line in Figure 23.5) reported in Fortier (2007). These initial gravimetric studies involving 10 mg IAC samples containing $ZnCl_2$ or K_2CO_3 showed that the method may be used for combinatorial screening.

23.3.1.2 Examining the Impact of the Sequential Addition of the Impregnating Solutions

Traditional bulk impregnations usually involve premixing of all the components of the impregnating solutions prior to addition to the carbon. For example, a known recipe that is composed of HNO_3, $Cu(NO_3)_2$, and $H_3PO_4(MoO_3)_{12}·25\ H_2O$ (PMA) are homogenously mixed prior to combining with untreated AC and decomposition (Smith 2008). The simultaneous addition of the components of the impregnating solution cannot be achieved using the solutions handling robot. The corrosive nature of the impregnating solution dictates that: (1) HNO_3 pretreatment of carbon is performed and (2) that the components are sequentially added onto the HNO_3 pretreated AC (Romero et al. 2010). The addition of HNO_3 ensures the even dispersion of the impregnants on the surface of the carbon and is also important in the deposition of nanoscale-sized impregnants as reported in previous studies (Smith 2008, Smith et al. 2009). HNO_3-treatment on carbon was also found to increase the adsorption of NH_3 on the adsorbent (Le Leuch and Bandosz 2007, Olong et al. 2007). However, the exact mechanism of how HNO_3 treatment affects the binding of the impregnants onto the activated carbon substrate is not yet fully understood. It was also reported that IACs containing CuO and $H_3PO_4(MoO_3)_{12}·25\ H_2O$ are efficient adsorbers of both SO_2 and HCN gases (Le Leuch and Bandosz 2007). To determine the effects of the sequential addition of components, samples were impregnated using a modified version of the traditional impregnation method as described in Section 23.2.7 and challenged with SO_2 gas. SO_2 gas was chosen due to the known adsorption reactions with CuO according to Equation 23.4 (Smith 2008, Romero et al. 2010). Table 23.1 shows the samples prepared to investigate the effects of the sequential addition of each component. Sample 1 was prepared exactly as described in Section 23.2.7 while samples 2–5 were prepared by addition of the first component (Impregnation 1 in Table 23.1) followed by the second component (Impregnation 2 in Table 23.1). Table 23.1 also shows that the calculated SO_2 capacity and the stoichiometric ratio of reaction (SRR) between SO_2 and CuO. Results show that the values calculated for the samples were similar and did not deviate significantly from the values obtained for the sample prepared traditionally. This implied that the there is no impact in the adsorbent performance whether each component is added sequentially

TABLE 23.1

Samples Prepared to Determine the Effects of Sequential Imbibing

Sample Number	Method of Impregnation	Impregnation 1	Impregnation 2	SO_2 Capacity (mmol SO_2/g AC)	SRR (mol SO_2/mol CuO)
1 Control	Bulk, traditional	Premixed $Cu(NO_3)_2$[a] and PMA[b]	N/A	0.95	0.60
2	Bulk	$Cu(NO_3)_2$[a]	PMA[b]	1.00	0.58
3	Bulk	PMA[b]	$Cu(NO_3)_2$[a]	0.97	0.54
4	Combi	$Cu(NO_3)_2$[a]	PMA[b]	0.95	0.54
5	Combi	PMA[a]	$Cu(NO_3)_2$[a]	0.95	0.54

[a] $Cu(NO_3)_2 \cdot 2.5\ H_2O$.

[b] $H_3PO_4(MoO_3)_{12} \cdot 25\ H_2O$.

or premixed. This further validated that the combi method can be used to effectively screen for new adsorbent materials.

$$CuO\ (s) + SO_2(g) \rightarrow CuSO_3(s) \tag{23.4}$$

23.3.2 Combinatorial Synthesis of $Cu(NO_3)_2$, $Zn(NO_3)_2$, and $H_3PO_4 \cdot (MoO_3)_{12}$-IACs

Traditional impregnants were used to demonstrate the usefulness of the combinatorial method to screen for the gas adsorption abilities of IACs. Zinc and copper nitrate impregnated samples of varying composition were used to evaluate the combinatorial approach for screening multi-gas adsorbent materials. An 8 × 8 array of CuO and ZnO IACs containing different proportions of metal oxides was combinatorially prepared along with $H_3PO_4(MoO_3)_{12} \cdot 25\ H_2O$ by adding increasing amounts of $Zn(NO_3)_2$ (x-direction) and $Cu(NO_3)_2$ (y-direction) in two dimensions and adding a constant amount of $H_3PO_4(MoO_3)_{12} \cdot 25\ H_2O$ (in all 64 samples) onto HNO_3 pretreated ACs (Romero et al. 2010). The nitrates were decomposed to the corresponding metal oxides according to the procedure described in Section 23.2.4. Powder XRD analysis of the unexposed impregnated samples showed diffraction patterns consistent with having CuO and ZnO on the activated carbon which proved that the impregnants were fully decomposed after the heating cycle (Romero et al. 2010). The CuO and ZnO IAC materials were evaluated gravimetrically for their ability to adsorb SO_2 gas when exposed for 4 h. The increase in mass of the IACs after being challenged with SO_2 is presumed to be due to the reaction between the metal oxides and SO_2 to form either copper or zinc sulfites. When the SO_2 exposed impregnated samples were soaked in water and the liquid recovered by filtering, $CuSO_4$ and $ZnSO_4$ salts (identified by XRD) were obtained upon drying the filtrate. The presence of these salts in the recovered filtrate proves that SO_2 was captured by the adsorbent (Romero et al. 2010).

It was observed that the absorption capacity of the IAC increased as the amount of both Cu and Zn impregnants was increased (Romero et al. 2010). The increasing trend observed in the adsorption capacity of the material indicated that the removal of the toxic SO_2 gas is dependent on the metal loading. The study also proved that Zn can be used interchangeably with Cu and worked as an effective SO_2 adsorbent. No trend was observed in the NH_3 adsorption capacity of these materials with increasing CuO content, however, it was observed that NH_3 adsorption increased as the amount of ZnO was increased (Romero et al. 2010). The exact mechanism of NH_3 gas adsorption onto ZnO requires further studies.

23.3.3 Combinatorial Screening of Multicomponent IACs

23.3.3.1 Combinatorial Screening for Potential Gas Adsorbent Active Precursors

The combinatorial method was used to screen for potentially gas adsorbent active materials. Inorganic precursors such as chlorides, acetates, and sulfates of other transition metals such as, Co, Mn, Fe, Ni, Cu, Zn, and Al have been studied using a modified combinatorial method to determine the ability of single component IACs to remove SO_2 and NH_3 gases. It was necessary to find components with maximized gas adsorption capacities at an impregnant loading of about 2.4 mmol impregnant/g AC using a single impregnation step which is typical of most of the Cu-based IACs (Smith 2008). Impregnant loading larger than this value affects the ability of the activated carbon to adsorb organic vapors. Figure 23.6 shows the SO_2 (panels a–d) and NH_3 (panels e–h) gas adsorption capacities of these single component IACs. Figure 23.6 shows that metal nitrates, chlorides acetates, and sulfates have been screened for their potential as gas adsorbent species. Through powder XRD analysis, it has been determined that decomposition at a temperature of 200°C fully decomposed the metal nitrates into their metal oxides while for the chlorides, acetates, and sulfates, only solvent removal was observed when heated at 200°C. The performance of each component to adsorb SO_2 and NH_3 gases was compared to the performance of a commercial off-the-shelf multi-gas adsorbent known as URC.

It was determined that most of the metal acetates and metal sulfates have limited solubilities, therefore the desired impregnant loading could not be reached in just a single impregnation step and may not perform as desired when used in gas adsorption applications. Furthermore, their performance as SO_2 and NH_3 adsorbents does not surpass that of URC with the exception of metal sulfates which have the potential to surpass URC in NH_3 gas adsorption (Figure 23.5h). The metal nitrates and the metal chlorides were

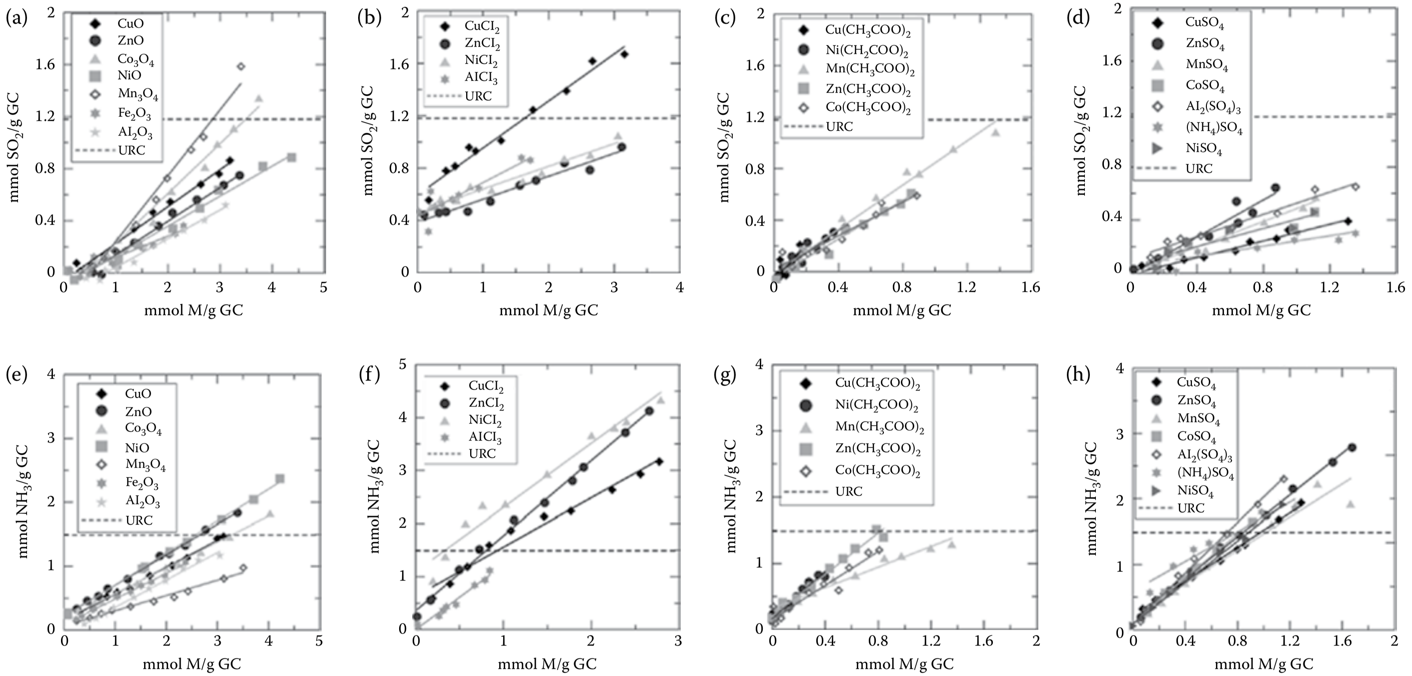

FIGURE 23.6
Panels (a)–(d) show the SO_2 capacity of single component IACs using various metal precursors. Panels (e)–(f) show the NH_3 capacity of these materials. Note that due to the high NH_3 adsorption capacity of chlorides, the scale for panel (f) is different than panels (e), (g), and (h).

found to be the most useful precursors for multicomponent IACs as that the desired material loading could be reached using a single impregnation step.

23.3.3.2 Ternary Metal IACs

Among the materials tested, Mn_3O_4, $CuCl_2$, and NiO show potential as a co-impregnant with Cu and Zn. In the study of multiple ternary systems, these impregnants were incorporated with CuO and ZnO to form three component IACs. The study showed that CuO/ZnO/$CuCl_2$ combinations have the potential to adsorb acidic and basic gases (Romero et al. 2011a, b). Furthermore, studies have shown that CuO/ZnO/Mn_3O_4 IACs have a greater ability to adsorb SO_2 compared to CuO/ZnO/NiO combinations (Romero et al. 2013).

23.4 Conclusions

It was demonstrated that it is possible to apply combinatorial methods to assess the performance of IAC materials in a high throughput manner in order to determine their viability as respirator materials. The method enabled us to study a large number of samples with varying compositions which allowed us to identify a unique combination of materials that was never reported to possess versatile gas adsorption properties.

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24

US Air Force Respiratory Protection Studies

Joseph D. Wander

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24.1 Introduction

Research conducted by the US Air Force and various partners has made great strides in understanding the physical and biological mechanisms involved in respiratory protection. This chapter summarizes some of the highlights of this work and offers suggestions on where additional research may be focused.

24.2 Evaluation of Reactive Antimicrobial Filter Technologies

In 1999, a Canadian–American company filed a patent application (Moorehead et al. 2003) for a novel antimicrobial treatment applicable to filtering facepiece respirators (FFRs) for individual respiratory protection (IRP). The active principle—a polystyrene resin functionalized as a quaternary amine and paired with triiodide- and larger polyiodide complexes—had been established as an effective agent in water (Taylor et al. 1970) three decades earlier and shown to release iodine on demand to impinging microbes. Congressional Interest funding started in 2004 and initiated an Air Force Research Laboratory (AFRL) project to evaluate this technology.

In experiments in which FFRs were sealed to a jig and bioaerosol-laden air was drawn through the medium, 2- to 4-log attenuation of viability of microorganisms penetrating the filter was consistently observed for a wide spectrum of bacteria and viruses as evaluated in culture. Contact activation, as in water, would capture the particles on the filter, and background iodine concentrations measured in the absence of penetrating particles were too low to be effective. In collaboration with the University of Florida, Ratnesar-Shumate et al. (2008) conceived a demand–release mechanism by which surface charges on the microorganisms draw iodine from the polyiodide complex during near approach to the treated fiber (Figure 24.1).

The reactivity of iodine set a couple of traps that are retrospectively obvious but that invalidated a generation of biocidal assays (Messier et al. 2002, Ratnesar-Shumate et al. 2008). Lee et al. (2009) recognized the first pitfall—that culture assays are carried out in water, in which Taylor et al. (1970) have established the biocidal efficacy of the triiodide complex, and which obliterates any preceding influences. The upside of this realization is that it supports the near-approach–capture mechanism because the background I_2 concentration is too low to be effective. To isolate the aerosol-phase effect of captured iodine on viability, iodine-laden MS2 particles were collected in 2-L chambers prepared from food storage bags and allowed to incubate at room temperature for times from 1 to 10 minutes. Next, the bioaerosol was drawn into an impinger containing a solution of sodium thiosulfate, which immediately (2009) quenched the iodine and isolated the effect of iodine in the aerosol phase. Relative humidity was a significant factor—$t_{1/2}$ for the untreated control was ~10 min at ~90% RH, and effectively infinite at RH less than 60%. Below 35% RH, $t_{1/2}$ for iodine-laden MS2 was ~8 min; at RH 45% and up, $t_{1/2}$ was ~1 min (Heimbuch et al. 2015). A control experiment showed that the plastic of the bag absorbs free iodine, so the kinetics should be reexamined in an inert container; however, that efficient kill was achieved implies

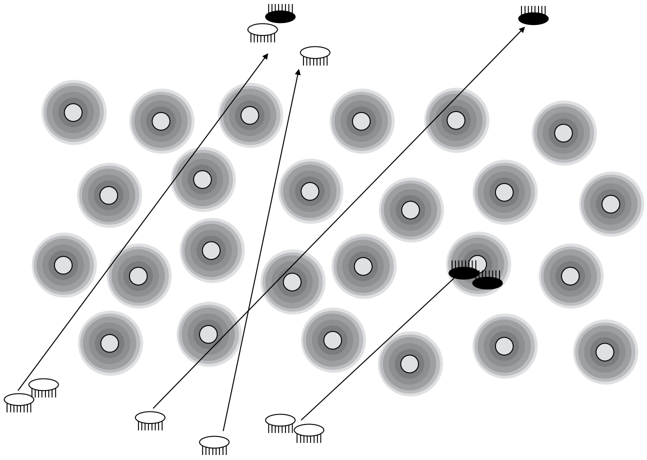

FIGURE 24.1
Capture of I_2 from filter fibers by penetrating bioaerosol particles.

that competition by the bag for captured iodine was minor or insignificant in contrast with the interaction with proteins. The inference from this exercise is that the value of the captured iodine for IRP is at best uncertain, whereas it may have virtue in HVAC applications, for which residence times at six changes/h are ~10 × $t_{1/2}$.

The 2006 Institute of Medicine (IOM) reports that opened the idea of cleaning and reusing FFRs during epidemics led to development of two categories of viral aerosol delivery methods. The National Institute for Occupational Safety and Health (NIOSH) (Fisher et al. 2009), University of Florida (Woo et al. 2010), and University of Nebraska Medical Center (Lore et al. 2011) teams developed mixing chambers to deposit a reproducible, selected loading of viral particles onto coupons of FFR medium, uniform to less than 5% variation, to support evaluation of decontamination methods. AFRL's technical support contractor assembled the Lab-Scale Aerosol Test system (LSAT, Figure 24.2) (Heimbuch et al. 2010, ASTM 2016), to challenge FFRs with infective aerosols and quantify viable removal efficiency (VRE). The FFR medium mounts across the

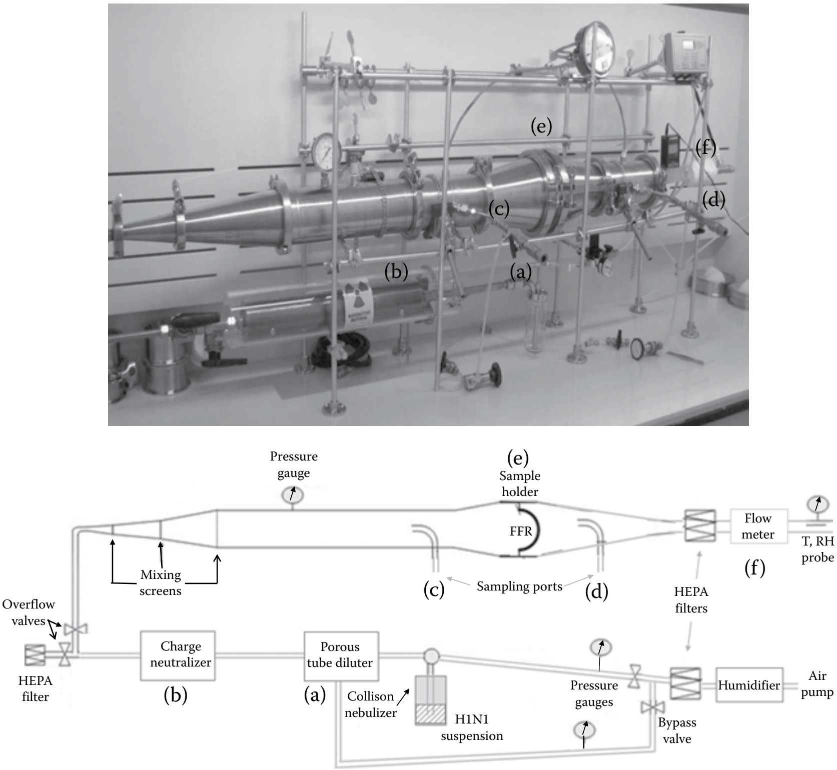
(e)
(f)
(c)
(d)
(b)
(a)
Pressure gauge
(e)
Sample holder
FFR
Flow meter
T, RH probe
(f)
Mixing screens
(c)
Sampling ports
(d)
HEPA filters
Overflow valves
HEPA filter
Charge neutralizer
(b)
Porous tube diluter
(a)
Collison nebulizer
H1N1 suspension
Pressure gauges
Bypass valve
Humidifier
Air pump

FIGURE 24.2
Photograph (top) and schematic (bottom) of LSAT; components labeled (a)–(f) in the photograph are identified in the schematic.

cross section of the expanded region, and VRE is determined from the ratio of viable counts captured and plated from sampling ports before and after the expanded region. Numerous industrial-scale and home-usable approaches to decontamination of N95 FFRs were tested using these and similar devices and ethylene oxide (EO) and several applying UV light or water vapor and heat or power were shown to achieve multilog reduction in residual viable counts (Heimbuch et al. 2010, Fisher et al. 2011) without compromising fit (Bergman et al. 2011) and VRE (Bergman et al. 2010) performance below NIOSH's criteria for new-article approval, even after several cycles of decontamination. Hypochlorite was effective (Fisher et al. 2011) and created no toxic residues (Salter et al. 2010), but corrodes metal components. Given the associated risk factors, the technical case for cleaning and reuse in genuine crises appears clear, but regulatory agencies have yet to embrace the concept.

The second trap associated with iodine is that it is reactive, including with proteins, which has implications in two contexts. Eninger et al. (2008) collected MS2 bioaerosols that penetrated a medium containing the triiodide resin and detected no attenuation of viability of the phage because the protein medium on which they collected the aerosol consumed the iodine that the particles had captured. Lore et al. (2012) collected MS2 and *Bacillus atrophaeus* bacteria and spores penetrating conventional and triiodinated media and observed no biocidal activity, possibly a consequence of competition by the octamethyltetrasiloxane (Wolf and Stewart 1964) that was used as an antifoaming agent. Lee et al. (2009) established that competition caused by collection of iodine-bearing MS2 particles in a 3% solution of bovine serum albumin decreased effectiveness of the iodine by half. This medium simulates the coating on surfaces that inspired particles first encounter, a factor that complicates the task of evaluating the clinical significance of the iodine chemistry. To address that question, the AFRL team was fortunate to fall into another Congressional Interest item to develop a method to evaluate other antimicrobial FFR technologies, which initiated collaboration with the University of Nebraska Medical Center.

Stone et al. (2012) modified the LSAT (Figure 24.3) to deliver a controlled bioaerosol concentration to mice through a respiratory protection medium into a nose-only inhalation exposure system (NOIES) (Jaeger et al. 2006). Samples to measure air concentrations were collected from the sampling ports on either side of the medium immediately before and after each mouse exposure session.

McDonald et al. (2012) measured weight loss of three species of mice (two inbred strains, BALB/c and C57BL, and the semi-outbred strain CD-1) 7 days after intranasal delivery of H1N1-A/PR8 at $\sim 5 \times 10^6$ or $\sim 5 \times 10^7$ $TCID_{50}$ to assay sensitivity to infection by the virus, and down selected to the less-expensive CD-1 mouse for evaluation as a biological detector of H1N1-A/PR8 concentration. After a week of conditioning to the enclosure, size-matched groups of three juvenile female CD-1 mice were exposed for a period of time of 2, 6, 20, or 60 minutes to one of three concentrations of H1N1-A/PR8 (1.5×10^6, 1.5×10^5, and 5×10^4 $TCID_{50}$/mL delivered as a polydisperse

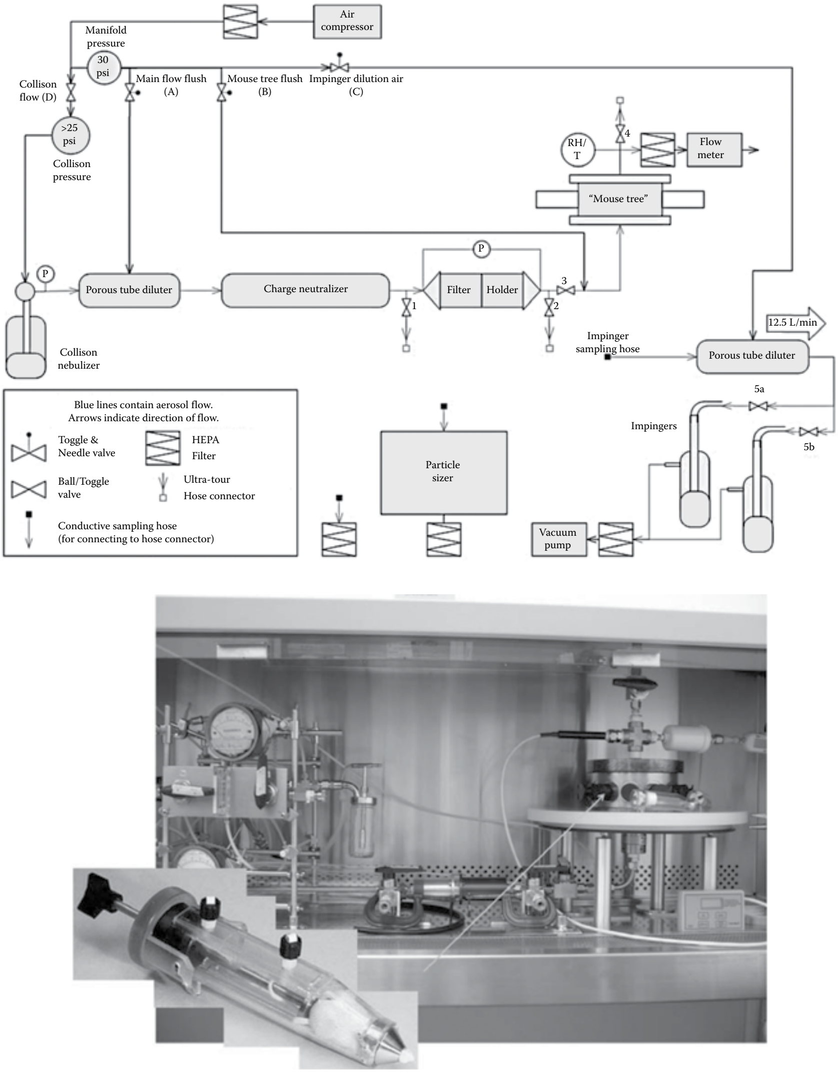
Air compressor
Manifold pressure
30 psi
Collison flow (D)
Main flow flush (A)
Mouse tree flush (B)
Impinger dilution air (C)
>25 psi
Collison pressure
RH/T
4
Flow meter
"Mouse tree"
P
P
Porous tube diluter
Charge neutralizer
Filter
Holder
1
2
3
12.5 L/min
Impinger sampling hose
Porous tube diluter
Collison nebulizer
5a
5b
Impingers
Blue lines contain aerosol flow.
Arrows indicate direction of flow.
Toggle & Needle valve
HEPA Filter
Ball/Toggle valve
Ultra-tour Hose connector
Conductive sampling hose (for connecting to hose connector)
Particle sizer
Vacuum pump

FIGURE 24.3
Schematic (top) and photograph (bottom) of controlled aerosol transmission system for mouse respiratory exposure. Inset shows a CD-1 mouse placed in an exposure cage.

aerosol from the Collison nebulizer) and weighed daily for 7 days or until distress became profound enough to indicate euthanasia. Aerosol concentrations were shown to remain constant for 2 hours. Survivors were sacrificed at the end of day 7 post exposure, necropsied, and dissected for histologic, molecular, and viral culture assessment. Virus in lung tissue homogenates was assayed by serial dilution on plates prepared with Madin–Darby canine kidney (MDCK) cells and microscopic examination for cytopathic effect

(CPE) or direct fluorescent antibody (DFA) evaluation. RNA was extracted from homogenates and amplified by cycles of polymerase chain reaction until detection; a cycle threshold (Ct) value of 30 or less was used as the criterion for infection. Tissue sections were fixed and stained with hematoxylin and eosin before inspection by light microscopy.

Dose was reckoned as a concentration-time product (Ct), so several (e.g., 1.5×10^6 $TCID_{50}$/mL × 2 min and 1.5×10^5 $TCID_{50}$/mL × 20 min) overlap. All 15 mice exposed to the highest aerosol concentration tested positive for infection by Ct, DFA, and CPE. Two of three mice exposed to the intermediate concentration for 2 minutes did not test positive by Ct. A further threefold dilution and shortened exposure times (3, 6, 9, 12, and 18 minutes) for groups of five mice (80% power to predict) was undertaken to bracket a threshold dose, which fell between 9 and 18 minutes. A calculation of aerosol concentration from nebulizer concentration set the ED_{50} at an exposure of 18–36 $TCID_{50}$, uncorrected for nonviables and absorption. In application, the increment of clinical effectiveness is expected to be the ratio of concentrations delivered from the nebulizer passing a control medium (or the open duct) and through the medium of the candidate IRP device that elicit a 50% infection rate in the mice, but this remains to be demonstrated for the triiodide–resin complex or other technologies claiming antimicrobial activity.

24.3 Individual Respiratory Protection: Cleaning and Reuse

The NIOSH-approved N95 FFR is the standard for IRP in environments that present a risk of respiratory transmission of infection. As manufacturing is typically maintained at or near capacity, predictions of a shortage during the next influenza epidemic prompted exploration of the idea of cleaning and reusing N95 FFRs (IOM 2006). FFR approval status from NIOSH would be lost, but the greater element of risk to teams working without any IRP in clinical and other venues that include influenza victims drove a series of evaluations supported by the Food and Drug Administration (FDA), Biomedical Advanced Research and Development Authority (BARDA), NIOSH (Viscusi et al. 2007), and the University of Nebraska Medical Center of the competence of N95 FFRs after cleaning by a range of methods.

A prerequisite to evaluating decontamination of a filtering medium—and any surface experiencing or at risk of microbiological contamination—is a reproducible method to apply a specified amount of contamination uniformly and reproducibly. Direct application of an inoculum does not reproduce the deposition of an infective aerosol, so NIOSH (Fisher et al. 2009) and the University of Florida–AFRL teams developed aerosol deposition chambers for viruses (Heimbuch et al. 2009, Woo et al. 2010) and microbes in general (Heimbuch et al. 2009, ASTM 2010, 2016) that achieved >95% reproducibility to support the evaluation of decontamination procedures. A separate method was also developed by a US Army–Air Force team for dry deposition of bacterial spores (Harnish et al. 2014) and capture of *Bacillus atrophaeus* spores by nine fabrics of possible use in individual protection was measured on a plate at three angles of incidence and three incident velocities and on a screen for perpendicular approach at the same three velocities (Sajo et al. 2015).

Availability of quantitative contamination methods enabled a series of investigations of approaches to decontamination of viruses from N95 FFRs. Components of some melted from direct microwave heating (Viscusi et al. 2009), commercial microwave steam bags achieved only 3-log attenuation of viability of MS2 phage (Fisher et al. 2011), and 1:10 dilutions of hypochlorite bleach were very effective against viruses (Fisher et al. 2009, 2011) and *Staphylococcus aureus* (Heimbuch et al. 2014), and preserved fit and function but corroded metal parts (Bergman et al. 2010) of some FFRs and some wearers reported a residual odor (Viscusi et al. 2009). However, no consequential amounts of toxic by-products were detected after treatment (Salter et al. 2010). EO and vaporous hydrogen peroxide (VHP) were both effective and tolerated by the FFRs (Viscusi et al. 2009), yet EO reacted with rubber straps to produce unidentified by-products (Salter et al. 2010). EO and VHP are industrial processes used in medical facilities but unavailable to individual users (Viscusi et al. 2009).

Among user-accessible options, ultraviolet (UV) irradiation is simple to apply and effectively germicidal without serious compromise of performance by the filter medium or respirator fit and wearability (Viscusi et al. 2011, Lore et al. 2012, Lindsley et al. 2015). Woo et al. (2012) showed effectiveness of UV decontamination to be independent of humidity but strongly suppressed by added proteins, and Lindsley et al. (2015) found a measurable decrease in FFR component mechanical strength after UV irradiation. Two options even more accessible to users use water to transfer energy: microwave-generated steam (MGS) and moist heat (MH, pasteurization). Each was found to be an effective virucide against H5N1 influenza (Lore et al. 2012) and to preserve fit and wearability. Solutions of hydrogen peroxide (3%), of dimethyldioxirane (DMDO, a biocidal cyclic peroxide generated *in situ* from acetone (Wallace et al. 2005)) and of its precursor oxidant, potassium persulfate (as Oxone™, a mixture containing ~40% $KHSO_5$) were shown not to contaminate FFRs above personal exposure limits (Salter et al. 2010).

The FDA supported a study of cleaning, vice decontamination, of FFRs in which three commercial cleaning wipes—one containing hypochlorite, one a quaternary ammonium disinfectant, and one only a mild surfactant—were used in a standard protocol to measure removal of mucin and disinfection of *S. aureus*, both applied to the inner face of FFRs. Analysis of coupons cut after cleaning showed the inert wipe cleaned best (~90% removal of mucin and bacteria), but the other two achieved 3-to-5-log bacterial decontamination (Heimbuch et al. 2014).

As repeated decontaminations of FFRs might be necessary during an epidemic event, eight methods considered potentially suitable for this use (UV, EO, VHP, hydrogen peroxide plasma, MGS, bleach, 3% hydrogen peroxide, and MH) were applied three times to a panel of NIOSH-approved N95 FFRs. The plasma method degraded filtration efficiency below 95% at 300 nm, but treatment with all seven of the others left the FFRs variously degraded but still competent and wearable (Salter et al. 2010). Fisher and Shaffer (2014) presented a consideration of various aspects of extended wear and limited reuse during shortages.

24.4 Individual Respiratory Protection: Fit and Leakage

Both leakage around and particle removal efficiency through a respirator are affected by the rate of air movement, and human panel testing of fits is limited by fatigue and variability among subjects. With support from BARDA, AFRL commissioned and, in cooperation with NIOSH, guided development of an articulated headform (Wander et al. 2012, Bergman et al. 2014) with a compliant skin matching the thicknesses measured at various locations on human faces (DeGreef et al. 2006) and a variable-rate and -profile breathing machine (Figure 24.4). This device was capable of operations at rates from 13 inspirations/minute (IPM) at a mean minute volume (MMV) of 10 liters/minute (LPM) to 75 IPM at a MMV of 150 LPM and a maximum instantaneous flow of 400 LPM (Balzli et al. 2016) to standardize fit testing and to enable leak testing with materials incompatible with human participation, at both normal and extreme respiration rates. Fits of representative models of FFRs on a static model of the headform (Figure 24.5) assembled as a prototype were measured (Figure 24.6) and compared to fits on a panel of human volunteers (Figure 24.7) under a modified protocol that included a normal and a deep breathing pattern. Linear regression by respirator showed a correlation of 0.95 and a difference in passing rate (fit factor <100) between the headform and humans of <20% (Bergman et al. 2015). In a study using the headform, He et al. (2014) measured inward leakage of paper, wood, and plastic combustion aerosols at three mean inspiratory flow rates from 30 to 85 LPM and five breathing rates from 10 to 30 respirations per minute.

24.5 Basic and Exploratory Collaborative Studies

Whereas polystyrene latex (PSL) spheres reaerosolize from AGI-30 impingers at an increasing rate as the passage of air continues, the rate at which MS 2 phage virus reaerosolizes rises briefly, and then falls off progressively. Riemenschneider et al. (2010) explained this phenomenon as caused by aggregation of virions after the concentration reached a critical value. Collection

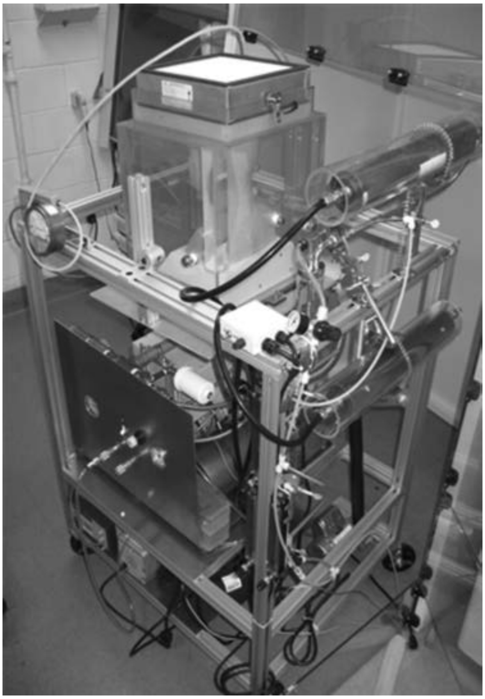

FIGURE 24.4
Breathing machine.

efficiency in the AGI-30 is poor for particles around 100 nm. To improve efficiency of capture of MS2 phage particles, Oh et al. (2010) attempted to grow nanoparticulate bioaerosols by condensation of a water-saturated dispersion in a cooled stage. Pan et al. (2016) recently reported growth of MS2 particles from <500 nm to 2–5 μm in a redesigned device. Ibrahim et al. (2015) delivered dispersions of H1N1 in a medium containing egg allantoic fluid through 1-, 3-, and 6-jet Collison nebulizers at 2 LPM per jet and measured the particle size distribution (PSD) at intervals to 60 minutes. After 60 minutes the viral titers were unchanged from initial values, but count median diameters declined from ~38 nm at 2 Lpm total delivery to ~32 nm at 12 Lpm total delivery, and particle counts increased by ~20%, attributed to a combination of evaporation and fragmentation of nonviable material.

Numerous studies have reported consistently that collection of biological particles is more efficient than inerts by a statistically insignificant amount. A BARDA-supported project challenged N95 FFRs sealed to a plate to eliminate leakage with aerosols containing H1N1-PR/8 and with 800-nm PSL spheres, which displayed similar PSDs. Median tissue culture infective dose ($TCID_{50}$) measurements with MDCK cells demonstrated viable removal efficiencies (VFEs) $\gg$95%, validating that the N95 FFR affords effective protection when properly fitted (Harnish et al. 2013). A second study, conducted in

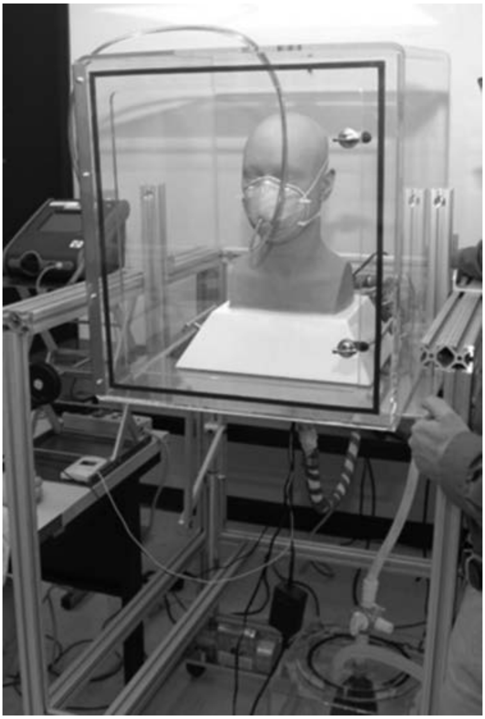

FIGURE 24.5
Respirator test apparatus.

water plus enough mucin to produce a mean particle size of 100 nm, showed that N95 FFRs afford effective protection against infectious particles as small as a bare influenza virion, and that viable and mechanical capture efficiencies are effectively the same independent of particle size (Harnish et al. 2016).

The final study reported (Heimbuch et al. 2016) from the AFRL team was a field study supported by Bay Medical Center, Panama City, Florida. Two

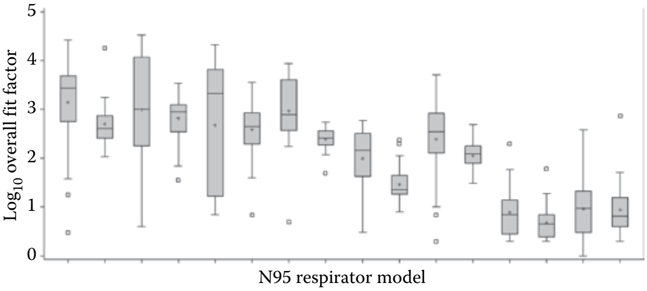

FIGURE 24.6
Box plots of (simplified protocol) fit factors measured with modified Portacount system for 16 models of N95 FFRs.

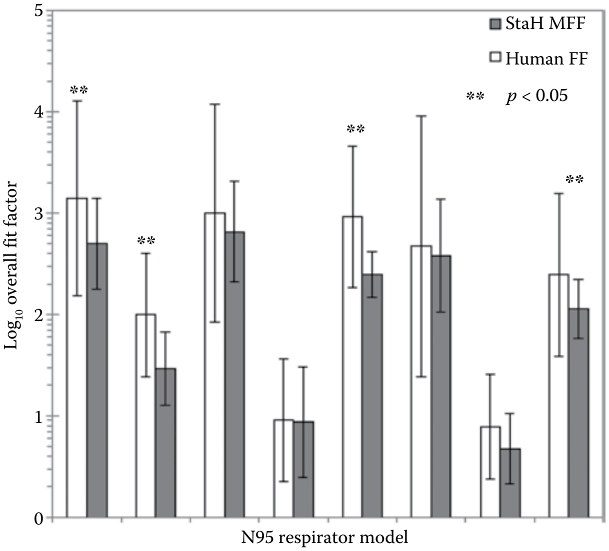

FIGURE 24.7
Comparison of (simplified protocol) fit factors measured for six models of N95 FFRs worn by the static headform and by human volunteers.

groups of staff members volunteered to double glove and wear an N95 respirator for the 20–30 minutes spent cleaning recently vacated patient rooms. The first glove was removed prior to doffing the mask, and samples were stored on ice for a day prior to punching of coupons and sonication in sterile water. Bacterial counts of $0.8 \pm 0.6 \times 10^4$ colony-forming units (CFUs) per respirator were calculated, of which a sampling showed oxacillin resistance in more than 2/3 and vancomycin resistance in almost 10%. PSD was not measured but only 3% of the bacteria reached the filter stage, indicating rapid evacuation of fines by the HVAC system and suggesting possible value for a simple fabric stage worn outside patient contact environments. However, no controls were run and no clean environment was available, so follow-up studies are clearly indicated.

Acknowledgments

Most of the work described above was conducted by a dedicated and skilled team of contractors provided by Applied Research Associates, Panama City, Florida. Generous support was provided by BARDA, FDA, and the Defense Threat Reduction Agency. Collaborations with the University of Florida, the University of Nebraska Medical Center, and NIOSH enabled much of this work.

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